Gallin, John 2019

Dr. John Gallin Oral History 2019

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This is an oral history with Dr. John I. Gallin about his career at the National Institutes of Health (NIH), conducted on March 11, 18, and 27, 2019, in the NIH Library. The interviewer is Victoria Harden, Founding Director, Emerita, of the Office of NIH History and Stetten Museum.

Harden: Dr. Gallin, would you begin by stating your full name, and that you know that this interview is being recorded, and that you give your permission for the recording?

Gallin: My name is John Isaac Gallin, and I give permission for the recording.

Harden: Thank you. Now, let's start at the beginning. You were born on March 25, 1943, in New York City, the second of two boys in your family. Would you begin by talking a bit about your family and your education through high school?

Gallin: Certainly. I was born in New York City, and I lived there with my family until I was five years old, when my family moved to New Rochelle, New York, which is about an hour outside New York City.

My dad [Nathaniel Mitchell Gallin] was an attorney, and he practiced law in New York City, so he would commute every day from our home into New York City by train, and then he'd come back every evening. My mom [Helen Ruth Cohen Gallin], who was trained as a social worker after I was born, went full time into taking care of her children as a mother and a wife. I went to public schools. I went to a school called Roosevelt Elementary School, and then I went to Albert Leonard Junior high school and then New Rochelle High School, a large public school serving the entire town of New Rochelle, New York, which was pretty large. After high school, I went to Amherst College.

While I was in school, I had particular interests going all the way back to elementary school. My favorite topic in those days was science, but I was particularly interested in minerals. I was fascinated by the crystal structure of minerals, and when I was five years old, I found my first crystal, a garnet crystal that was about a centimeter large. That finding excited me, and I still collect crystals and minerals to this day.

That was the beginning of my interest in science, and it seemed that all through my education in high school and junior high school, science was my favorite topic. It was what I focused my interest on. When I went to Amherst College--I felt very lucky to get there and to become part of that community--I continued with my interest in science. At Amherst, we had a required curriculum. During the first year, every student took the same required courses. They included English composition, physics, as well as a heavy dose of math--calculus, which I did okay in, and liked. I majored in biology, and in my senior year in college, I did an honors thesis in biology studying the bacterium *Sporocytophaga myxococcoides*. This bacterium was an interesting organism because it changed from a rod shape to coccus shape, and the project was to figure out how that happened and what regulated it.

Harden: I want to back up for a moment. Didn't you also do some research before that project with Dr. Paul J. Van Der Mark, or was this research with him?

Gallin: Let me even go back further. A very important event happened to me in college. In addition to science, I was also interested in some sports, and I played ice hockey. I had played ice hockey and was the team captain in high school, and then I played ice hockey my first two years in college. One day, a puck hit me in the mouth, and I lost my front teeth. I was knocked unconscious, and when I woke up, I picked up my teeth, went to the dentist and they implanted them back in my mouth. That was when I decided that maybe I wasn't going to be a professional hockey player and I focused my energy on academic pursuits.

Also, during the summer of my sophomore year of college, when I was working as a counselor at Hudson day camp in New Rochelle, I re-met my wife to be, Elaine Klimerman [Elaine Barbara Klimerman Gallin] whose family lived in Yonkers, New York. Elaine and I actually first met when I was 16 and she was 15 years old at a beach club, and we had our first date then, but then we re-met later. Elaine was a student at Cornell University, and following that summer we visited each other regularly our third and fourth years of college. We've now (2019) been very happily married over 53 years and both pursed careers in science while raising our family.

Between my junior year and senior year in college, I was fortunate to receive a National Science Foundation fellowship to go to Cornell in Ithaca and work with Paul J. Van der Mark [Dr. Paul J. Van der Mark], a professor of microbiology. I had an opportunity to study oxidative phosphorylation in the microorganism *Streptococcus faecalis.* This organism presumably could not do oxidative phosphorylation because it was an anaerobic organism. However, we found evidence for oxidative phosphorylation in this organism, and I published my first paper while a senior in college. When I returned to Amherst for my senior year, I worked with my college mentor, another microbiologist named Edward Leadbetter [Dr. Edward R. Ledbetter]. Edward Leadbetter, whom we called Ed, was marvelous, and he was always in the laboratory. We would often work until 10 o'clock at night, and then we would go out for pizza. It was a phenomenally important educational experience. I wrote a thesis and received honors when I graduated from college for that work.

Harden: When I interrupted you, you were telling me about this one particular organism you that worked on? Would you finish that?

Gallin: My college thesis was to study *Sporocytophaga myxococcoides* which differentiated from a rod shape to a coccal shape. My project was to study what environmental factors influence the shape transformation. I described a number of products that the organism released that could trigger the transformation. Changes in the organism's environment, the oxygen level, the CO_2 level were also important. There was insufficient time to bring the project to publication, but the experience was terrific. My undergraduate research experiences at Amherst College and Cornell University were transformative for me and I knew I wanted to pursue research as a career path.

Harden: As you were finishing at Amherst—and you were doing very well since you graduated cum laude—you had all sorts of opportunities for graduate work. As I understand it, you applied to a number of Ph.D. graduate programs, but you ended up in medical school. Tell me about this.

Gallin: After my experience at Cornell in the summer, my mentor at Cornell, Paul Van Der Mark, kept telling me, "You should go get your Ph. D." He said that I should apply to Cornell. I applied to Cornell, and I was accepted early with a nice scholarship. That would have been the fall of my senior year at college. I called my parents, and very excitedly, I said, "This is what I think I'm going to do." My dad said, "Do you mind if we have lunch?" He drove up to Amherst from New York City, and we had lunch, and said, "Getting a Ph.D. would be great, but maybe you would have more opportunities in the future if you got a medical degree. Why don't you at least try?" It was now getting a little late to apply to medical school, but I did, and I was accepted at Cornell. This was a fabulous opportunity, and I moved to New York City to start medical school. So the reason I went to medical school instead of graduate school to get a Ph.D. was that my dad drove to Amherst from New York City to have lunch with me and urge me to apply to medical school. How lucky I was to have such a wonderful dad.

Harden: In June 1966 you married Elaine. Can you tell me a little more about her background and career as a scientist? I understand that you two published several papers together.

Gallin: Elaine was a biology major in college and then decided she was going to pursue a Ph.D. She was accepted into City University of New York at Hunter College, which was just up the street from where I was a medical student. She got her Ph.D. in physiology and did very well. Elaine became interested in electrical currents in cells. Later, after taking postdoctoral fellowships at Johns Hopkins and then at Columbia University, she became an independent investigator at the Armed Forces Radiobiology Research Institute in Bethesda, Maryland. In addition to her independent research, we collaborated on a number of projects related to membrane potential changes in macrophages and published in the *Journal of Cell Biology* and elsewhere. It was very exciting for us to work together on our research.

Harden: During your summers in medical school, you worked in several laboratories. One of these that apparently influenced you was run by microbiologist, Dr. William M. O'Leary. Would you tell me about Dr. O'Leary, and about your work in his laboratory?

Gallin: Dr. O'Leary was in the microbiology department at Cornell University Medical College, and he was a lipid chemist. When I worked with him, we were studying some microbial lipids. That was during the summer between my second and third years in medical school. We started looking at the relationship between host lipids of mammals and microbial infection. We challenged rabbits with bacteria (*Staphylococcus aureus*), and looked at changes in serum lipids. We noticed marked increases in triglycerides and free fatty acids and changes in cholesterol.

The following year, when I was a senior in medical school, I took a six-month elective in the Infectious Diseases division in the Department of Internal Medicine, with Donald Kaye [Dr. Donald Kaye]. Dr. Kaye later became Chairman of Medicine at Women's Medical College in Philadelphia. The chief of the infectious diseases division was Ed Hook [Dr. Edward W. Hook, Jr.], who later became Chair of Medicine at the University of Virginia in Charlottesville, and Gerry Mandell [Dr. Gerald L. Mandell], was his fellow who later became chief of Infectious Diseases at the University of Virginia. These folks were important mentors and we developed close friendships.

That environment during my infectious diseases elective my senior year of medical school was very important to me, because I began to become engaged in clinical infectious diseases as a medical student and started my career in clinical research. One of my jobs as a medical student was every Friday to present a patient with an infectious disease problem to a luncheon conference that Dr. Hook sponsored. At that conference, there were some very famous people, including Walsh McDermott [Dr. Walsh McDermott], who was an editor of a major textbook of medicine at the time[*The Cecil-Loeb Textbook of Medicine*] and head of the public health department in Cornell Medical School. Other attendees at the luncheon were James Hirsch [Dr. James G. Hirsch] from Rockefeller University, who was interested in phagocytic cells, and his colleague Zanvil Cohn [Dr. Zanvil A. Cohn], also at Rockefeller University, who was a leader in the field of macrophages in immunity.

I would present patients at these lunches. I learned how to present patients concisely. I got a free lunch, which was important, and then I would listen to these academic leaders talk about how much you could learn from the patients and how the patients could inform research directions. I also continued my partnership with Dr. O'Leary, and now with Donald Kaye, who was a terrific clinician. We asked the question whether the changes in circulating lipids I had seen in rabbits challenged with bacteria had any relevance to humans.

At night during medical school, I would go onto the patient care units and ask the house staff if it would be okay to draw blood cultures from any patient whom they thought might have an infection. Of course, they were thrilled to have someone who would do that for them. I would collect blood, and then I would say, "Oh, by the way, I want to take some of the blood to my lab and do some studies." They always said, "That's fine." There was no protocol in those days. You just did it. I would stay up late at night, analyzing the serum lipids from our patients. We had some interesting results showing that humans responded to infection much like the earlier studies we did in rabbits. We published a paper in the *New England Journal of Medicine* "Serum Lipids in Infection," and a nice editorial accompanied the publication.

We had several publications. I actually had two publications in the *New England Journal of Medicine* as a medical student. I didn't realize that it would be a long time after that before I had more papers in the *New England Journal of Medicine*. It was a very exciting time.

Harden: Indeed. Because of your work, you won two named memorial prizes during your senior year, one for research and one for infectious diseases. Would you explain whether they were given for those research projects or for something else?

Gallin: It was a thrill at graduation to get recognized for my research activities as a medical student. I received from Cornell the Dean William Mecklenburg Polk Memorial Prize in Research and the Anthony Seth Werner Memorial Prize in Infectious Diseases for the work I did as a medical student.

One other major event happened during my infectious diseases elective during my senior year of medical school. Dr. Hook introduced me to one of his visiting speakers, Sheldon Wolff [Dr. Sheldon M. Wolff]. Sheldon Wolff was working at NIH and was running the Laboratory of Clinical Investigation in NIAID [National Institute of Allergy and Infectious Diseases]. When Dr. Wolff came for one of the Friday lunches, Dr. Hook said to me, "Meet Dr. Wolff. He works at NIH, and you should work with him." I said, "Really? What's NIH?" I had no idea what NIH was, so they explained to me about the National Institutes of Health. Dr. Wolff was very interested in fever, and he was interested in the mechanism of fever. I applied to NIH because the choice was either to go to Vietnam in the military, or to join the U.S. Public Health Service, if you were lucky enough to be selected and to go to NIH as a Clinical Associate. As a member of the U.S. Public Health Service, you fulfilled your obligation for military service, and in addition you got trained in clinical research--in my case, in infectious diseases.

Harden: As I understand it, you made that application while you were still in medical school, before you did your internship and residency.

Gallin: That's correct. We applied in our last year of medical school, and I also applied to the Army to work at Walter Reed. I visited Walter Reed and had an interview there to work on a vaccine for gonorrhea. It was a wonderful interview, but the job was in the Army. It required wearing a uniform, and at lunch, all they talked about was the Vietnam war. When I went to NIH, the environment was different, more like a university. During my interview with Dr. Wolff, he asked "Have you had lunch?" I said, “No.” He said, "Come with me." We went down to the laboratory, and we did something you can't do anymore. He said, "Have you ever had Maryland crabs?" I said, “No.” We went into the lab and newspapers were spread on all the lab benches with mallets to break the crab shells, and people were smashing and eating the cooked crabs. That was my introduction to Maryland crabs. It also made it very easy to make the choice as to which environment I would prefer to be in, NIH vs Walter Reed.

On the first day of my internship at Bellevue, in July 1969, I was in the emergency room seeing a patient, my first patient I think, when I was paged for a phone call and I heard, "Hi, this is Sheldon Wolff. I'm calling to offer you a job at NIH and you have to tell me on the phone whether or not you accept it." There was no hesitation on my part. Elaine and I had two babies and NIH was exactly what I wanted to do, so I said, “Yes.” Then I called Elaine and said, "Guess what, in two years, we're going to Washington." She was thrilled, and so we came to NIH in Bethesda.

Harden: That's a wonderful story. Okay, tell me about your internship and residency. You were at Bellevue, about which I've heard a lot of people say that because it is a large public hospital, interns get to see “everything,” and it gives you a really good grounding.

Gallin: I was at Bellevue from 1969 to 1971 for my first tour. It was an internship and residency in internal medicine. Originally, three medical schools in New York contributed to the care at Bellevue because it was so large—Cornell, Columbia, and New York University (NYU). When I was a medical student at Cornell, I actually spent some time at Bellevue, so I knew it a little bit about the environment, and I applied there for my internship and was pleased to be accepted. By the time I went, it was exclusively an NYU enterprise. Columbia and Cornell were out. Bellevue was large, it was busy, and as an intern, you were given tremendous freedom in the care of the patients. What a privilege, opportunity and responsibility that was!

The people who oversaw the interns were the first-year residents, as well as the attending physicians. As an intern you were often alone at night with the patients, so you had a tremendous amount of responsibility given to you very early. When you were on the patient care units, you had to cover three places at once. You had to go to the emergency room when a patient arrived. You had to take care of that patient and stabilize them while you were continuing to take care of your 26 patients up on the ward. If you had any patients in the intensive care unit, you also had to take care of those patients in the intensive care unit.

You were very busy running around, doing all sorts of things. You drew all your bloods on your patients--nobody drew bloods for you. You sometimes had to walk the bloods over to the laboratory because the messenger service wasn't quite what it should be. Sometimes, I actually had to develop the chest x-rays. It was a very busy city hospital, where you saw virtually everything, and you were on call every other night, and often you did not sleep when you were on call. There is a family story about my daughter, Alice, who was in pre-school at the time. Alice’s class was asked by the teacher to describe what their fathers did. When it came to Alice, she said, "My dad sleeps." The teacher asked my wife if there something wrong with me. She laughed and explained about my schedule at Bellevue.

We were on call every other night and every other weekend, and when you were on every other weekend, you were there from Saturday morning to Monday night. You often didn't sleep. This has changed. Interns are no longer allowed to do that, but it was a phenomenal opportunity to follow the continuity of illness and care for one patient through the very critical stages of their illness.

Harden: I understand that during your internship Dr. Saul Farber was your chairman of medicine, and he became a mentor to you. Do you want to talk a bit about him?

Gallin: Dr. Farber was a legend. He was a phenomenal clinician. He spent a lot of time with his house staff, the interns and residents. He taught us medicine in an amazing way, and he also had a sensitivity to NIH. He was friends with Dr. Shannon [Dr. James A. Shannon] and knew NIH well, and he was very supportive of my going to NIH. He thought it was spectacular, and so during my internship and residency, he was one of the wonderful clinical mentors at Bellevue and NYU. When I was his senior chief resident a few years later, we became much closer.

After I spent two years at NIH, I went back to New York University/Bellevue as the Senior Chief Medical Resident. In that capacity, I met every day with Dr. Farber. There were three junior chief residents under me, and every Saturday, we would go for lunch at the local deli, which was across the street. After lunch, Dr. Farber would always ask me to come back with him to his office, and he would talk about whatever was on his mind, and I would talk about what was on my mind. One day around three o'clock in the afternoon on Saturday--and I could call him Saul at that point--I said, "Saul, I have two babies at home and if I don't get home, I won't have a family." He said, “Get out of here.”

Harden: Another person with whom you worked was Dr. Sherwood Lawrence. Would you tell me about him?

Gallin: Dr. Lawrence was chief of infectious diseases at the time, and he was a wonderful immunologist. He discovered transfer factor. Transfer factor was isolated from lymphocytes from a patient who had an immunologic reaction to something like tuberculosis. If the transfer factor were then injected subcutaneously into a patient naïve to tuberculosis, the recipient of the transfer factor would then become sensitized and exhibit a delayed hypersensitivity reaction to the tuberculosis. For his discovery of transfer factor Dr. Lawrence was elected to the National Academy of Sciences. People are still studying it.

Harden: You worked with him.

Gallin: I worked with him as a house officer works with a head of a clinical division. I didn't work in the laboratory with him, but he was a great role model for doing clinical research. During my time at Bellevue, I served on the tuberculosis ward, and I got interested in tuberculosis. I decided that we ought to be able to make a better test for diagnosing TB. I had the privilege of working with Norton Spritz [Dr. Norton Spritz] chairman of medicine there at the Manhattan VA [Veterans Administration] hospital across the street from Bellevue. Dr. Spritz was a lipid chemist and I asked him, "Couldn't we develop a better test for TB?" We had the idea that you could take radioactive stearic acid and add it to a sputum culture with tuberculosis. There was a unique fatty acid in tuberculosis bacilli called tuberculostearic acid, and we speculated that you could monitor the incorporation of stearic acid into tuberculosteric acid using thin layer chromatography.

Every night, I would collect sputum from patients on Bellevue’s TB ward, carry them over to Dr. Spritz’s laboratory at the Manhattan VA, and set up the cultures. It worked. The problem was that this test for tuberculosis was a little less sensitive than a sputum smear, so it didn't go anywhere. But I learned a lot, and I did a lot. Unfortunately, during that experience, I contracted tuberculosis.

Harden: That came back to haunt you years later, did it not?

Gallin: Yes. I didn't know I had it until I was at NIH. It was after my third year as a Clinical Associate at NIH, when Surgeon General Koop [Surgeon General C. Everett Koop] wrote me a letter and said, "If you don't get a physical exam, we're kicking you out of the Public Health Service." So I got my physical, and on my chest x-ray, there an infiltrate in my lung. Shelley Wolff suspected I had tuberculosis because I had a very positive skin test and a dry hacking cough, but the diagnosis was not proven. I was placed on INH [Isoniazid] as I went back to Bellevue as the Chief Resident. I didn't like INH so I only took it for about six months, but I was fine. Then when I came back to NIH again, and my cough returned and coincidentally I got another letter from the Surgeon General saying, "You better get another exam," and that time there was a solitary pulmonary nodule in the middle lobe of my right lung. I went to surgery, had a thoracotomy, and that turned out to be tuberculosis in my lung. There was also an adenocarcinoma embedded in the infection, called a “scar tumor.” I was very lucky, because they took it out, and I took INH and two other drugs for a year and have been symptom free for over 25 years.

Harden: Everything was okay?

Gallin: I was very lucky.

Harden: You were very lucky. One other person during your internship residency that you worked with was Gerry Weissmann [Dr. Gerald Weissmann], who was a leader of neutrophil biology, and I believe he had an influence on your interest in phagocytic cells.

Gallin: He did. Gerry Weissmann was head of rheumatology at Bellevue Hospital. He was a really good phagocyte person and terrific at relating clinical situations to research opportunities. He was interested in how phagocytes worked, how they moved, how they ate and killed bacteria and, as a rheumatologist, how they caused inflammation. That was closely aligned to some of my earlier interests in infectious diseases. We talked a lot and had a lot of fun. One of the people who was a year ahead of me as a chief resident was Ira Goldstein [Dr. Ira M. Goldstein]. Ira Goldstein and I did some work together, and he worked with Gerry Weissmann directly. Later, Ira and I edited a text, *Inflammation: Basic Principles and Clinical Correlates,* with Ralph Snyderman, that went through three editions.

Harden: When did you begin to work on phagocytes, and how did you see that field develop as molecular biology differentiated various subsets of white cells?

Gallin: I started working on phagocytes when I came to NIH as a Clinical Associate in the U.S. Public Health Service. I worked with Harry Kimball [Dr. Harry R. Kimball] in Dr. Wolff's laboratory. Neutrophils were the most common white cells in the blood. Another prominent white blood cell was the monocyte. Monocytes are also phagocytic cells that migrate into tissues and transform into macrophages. I was fascinated with how neutrophils and macrophages migrated into tissues, ingested foreign particles such as bacteria and served an important role in host defense and in inflammation.

When I started in 1971 at NIH, I was given an opportunity to look at all the different sections within the Laboratory of Clinical Investigations. I chose to work with Harry Kimball, who was working on phagocytes. Sheldon Wolff was interested in host defense against infection, and he was brilliant in recognizing the role of the phagocytic cells, as well as the lymphocytes, in host defense against infection. He was also highly sensitive to the fact that if you bring in patients with unexplained problems with infectious diseases, some would likely have abnormal function of these cell types. That is what was done at the NIH Clinical Center, and some of these patients had problems restricted to their phagocytes. I was lucky to be in the early stages of caring for and studying the phagocytes of this group of patients.

During my first year at NIH I kept hearing about Tony Fauci [Dr. Anthony S. Fauci], who was then chief resident at the New York Hospital which was the hospital for Cornell Medical College. In July of my second year at NIH, Tony arrived at NIH, back from his chief residency, and he was given the laboratory across the hall from me. We became close friends.

My mentor Harry Kimball became ill during my first year as a Clinical Associate. When he was recovering from his illness he decided he didn't want to be a scientist, and he left NIH and went to Yakima, Washington, to practice medicine. He did that for a few years and later became chairman of the American Board of Internal Medicine in Philadelphia. The result of Dr. Kimball's illness and decision to leave NIH meant that I was without a mentor. Dr. Wolff said, "What do you want to do? Everybody needs a mentor." I said, "Well, I've had some past laboratory experience and published some papers. I would just like to use all the senior lab members as mentors. I'll go to different people when I have different problems." He said, "Okay," and so he gave me a small lab. I was very lucky. I was able to go to all these wonderful investigators in the Laboratory of Clinical Investigation as chiefs of different sections. I leveraged their skill sets to help me with my research.

Harden: What I'd like you to do next is to give me an even more detailed picture of the Laboratory of Clinical Investigation in the early 1970s. I have heard stories about Dr. Sheldon Wolff and about what a magnificent laboratory he ran, and how he really understood about the need to investigate the host instead of the infection. Tell me--give me a picture--of that whole laboratory when you were a Clinical Associate.

Gallin: Let me just say Dr. Wolff was indeed a marvelous leader. There were lots of lab chiefs at NIH in the late '60s, early '70s, but not a lot of them picked so many young people who turned out to be "winners" in clinical research. One day I asked him, "How do you figure out whom to accept?" The Clinical Associates program during the Vietnam war was very competitive. I mean everybody wanted to avoid Vietnam and every medical school was having their people apply. Shelly said, "It's easy. I want someone I'm going to enjoy saying good morning to every day." He said he wanted team players and he picked talented people who had past experience on teams, whether in athletics, academics or music.

Dr. Wolff picked senior people to work in the lab who had complementary interests. He strove to avoid creating a team with competing interests. The people who were here at that time included Alan Rosenthal [Dr. Alan S. Rosenthal], an electron microscopist who had one of the first electron microscopes in the institute and who studied macrophage/lymphocyte (T cell) interaction. There was also Chuck Kirkpatrick [Dr. Charles H. Kirkpatrick], who studied lymphocytes and was interested in what we call delayed hypersensitivity, how the body responds to things like tuberculosis with an inflammatory reaction; Michael Frank [Dr. Michael M. Frank], who was interested in complement and later replaced Dr. Wolff as Clinical Director and Laboratory Chief; Allen Kaplan [Dr. Allen P. Kaplan] who was Chief of the Allergic Diseases Section; and Herbert Reynolds [Dr. Herbert Y. Reynolds], who was interested in pulmonary diseases. Tony Fauci joined as a Senior Investigator my second year at NIH.

Many of the faculty and trainees became leaders in American medicine. My class of Clinical Associates, who arrived in 1971, had some phenomenally talented people who became these leaders. Across the hall from me was Charles Dinarello [Dr. Charles A. Dinarello], who discovered Interleukin 1. John Atkinson [Dr. John P. Atkinson] was another member of my class who later served as Chair of Medicine at Washington University in St. Louis. Peter Lipsky [Dr. Peter E. Lipsky], who worked with Alan Rosenthal, became editor-in-chief of the *Journal of Immunology* and later became a Scientific Director of the Arthritis Institute [National Institute of Arthritis and Musculoskeletal and Skin Disases (NIAMS)]. Jim Pennington [Dr. James Pennington], who was in my NIH class, was an infectious diseases person who became involved in some companies out in the West Coast. Then there was Michael Toren [Dr. Michael S. Toren], who became a cardiologist and Doug Levin [Dr. Douglas M. Levin], who became a practicing gastroenterologist in Chicago. Out of seven people who started with me as Clinical Associates, five pursued science as a career, and that's a pretty incredible record and typical of Sheldon Wolff's classes of Clinical Associates.

An important aspect of Dr. Wolff's environment was his attention to mentoring and caring about each of his Clinical Associates but also everyone else in the laboratory, whether Senior Investigators, Clinical Associates, technicians, or housekeepers. He cared about everyone's personal and professional experience. He and his wife, Lila Wolff, invited everyone to their home regularly for social events. The Laboratory of Clinical Investigation was a wonderful place to work. It was like family and fostered the best of all the participants in the laboratory.

Harden: As these people left NIH and became leaders in academic medicine, what they were doing, if I understand correctly, was teaching the NIH model of research to their students in academia.

Gallin: That's correct.

Harden: Clinical Associates sometimes cynically called themselves “Yellow Berets” because they did not go to Vietnam, but instead learned how to conduct rigorous clinical research. I have a colleague—who is a physician with a Ph.D. in history of medicine--who very proudly says of his medical school clinical training, "I was trained by a Yellow Beret," implying first-class rigorous training. This was a very intense period of training for you all, was it not? And most of these very bright people went into academic medicine after leaving NIH.

Gallin: It was a very bright community, but one of the wonderful things about the community was that you didn't feel like there was competition. You felt it was collaboration. I was spending many hours at NIH because I wanted to be at NIH. It was just a way of life. So yes, they were very talented, very bright people. We were all trying to learn something. Many of us were learning different things and then sharing what we were learning. We had mentors who were extra special, and one of Dr. Wolff's core strengths as a mentor was his insistence that we sustain our engagement with the patients.

He personally made rounds every day and demanded that we all make rounds every day also. If you didn't, you heard from him. Every Friday from nine in the morning until whenever, usually noon or one o'clock in the afternoon, we would make rounds on every patient on the two wards on the 11th floor, the east and the west wings of the Clinical Center. We would go into great depth discussing every patient. One of the luxuries we had was time because we never had to worry about billing. The portfolio of patients was phenomenally exciting. They included patients with fever of unknown origin, some of whom were the first patients with phagocyte defects that had not previously been described. The interface of the clinical care of the patients and the research activities generated new questions to work on in the laboratory. It was Dr. Wolff who really made the lab environment so successful.

Harden: One question that I ask every physician is, “What was it that led you to want to do research as opposed to public health or private medicine?”

Gallin: That's a great question. For me, I think it was my many years--probably going all the way back to elementary school—of fascination with science and the idea that you could do something first. There's a real high with that, and it's a thrilling experience. Also, it helped that my wife Elaine shared the passion for science. When we came to NIH, she took a postdoctoral fellowship at Johns Hopkins, with a person who studied the retina. She learned how to do electrode recordings on single cells, and then she worked in the physiology department at Columbia University when I went to Bellevue as Chief Resident. Then she worked for a number of years across the street from NIH at the Armed Forces Radio Biology Research Institute and was among the first to use the technique of patch clamping, which is a sophisticated way to study membrane potential in single cells.

I convinced her that she should study some of the cells that I studied. She was among the first in the world to patch clamp macrophages, defining their membrane potentials during different conditions. One of the studies we did together that was published in the *Journal of Cell Biology* was on the effect of chemoattractants on human macrophage membrane potential. We had a lot of fun together. We'd come home at night, and our kids would say, "You can't talk about this stuff at dinner!" It was very important to us when we came to Bethesda to figure out how to create an environment that would be good for the family. The first challenge was where to live and we decided to live close to work. That's what we did, and if something was wrong with a child, one of us could get home quickly. If one child had to go do something, we could handle it. The kids never complained, or not too much, except when we talked too much about science at dinner.

Harden: You talked about interviewing with both LCI at NIH and with Walter Reed, but I remember that you also interviewed with Donald Fredrickson [Dr. Donald S. Fredrickson], who had a lab in the Heart Institute, but you decided against taking a position in his laboratory.

Gallin: Yes, that is correct. Because I had worked on lipids as a medical student, I interviewed with Dr. Fredrickson and his colleague Robert Levy [Dr. Robert I. Levy], who were the lipid mavens here at NIH. They described how cholesterol and triglycerides were important in heart disease. I recall that during my interview with Don Frederickson, he asked me "Why are you interested in infectious diseases?" I said, "Well, I'm interested in microbes and I had a research experience in medical school." He said, "There's no point in studying infectious diseases. The antibiotics are here. Why are you going to waste your time doing that? Come work on the importance of lipids in heart disease." I liked Don Fredrickson and his laboratory, but I chose to work with Dr. Wolff because of the connection of his laboratory direction with my clinical interests.

Harden: Tell me about the research you personally conducted during these first four years, when you said that nobody really understood what you were doing, and you remembered that a colleague asked you why you were doing work on neutrophils because it would never be clinically relevant.

Gallin: I won't tell you who said that.

Harden: No? Okay.

Gallin: The person who said that became a well-known investigator. Neutrophils were considered the stupid cells because they were like the pawns in chess. There were lots of them, and they would go out and fight the wars against bacteria. They would go out into the tissues, kill the bacteria, and then they would die. People argued that they were not the smart cells. The smart cells were thought to be the lymphocytes that have a memory and can remember previous infections, especially the subset of lymphocytes called B cells that make antibodies. Macrophages were long lived cells living in tissues such as the lungs and in the many organs. There are more neutrophils in the blood than any other white blood cell. And neutrophils are the most agile at locomotion—an important physiologic process of host defense. Neutrophils were long recognized as a cornerstone in the process of inflammation and it was known that absence of neutrophils had a devastating consequence on host defense.

I first studied neutrophil chemotaxis, which is their directed migratory response to a chemical stimulus. One of my first projects at NIH was to develop an improved assay for chemotaxis so we could compare cells from patients with normal subjects. We had this idea that if you took the cells and labeled them with a little radioactive chromium, you could then put them into a chamber, with two filters, an upper filter and a lower filter and a chemoattractant would go on the bottom. The cells would crawl through the upper filter into the bottom filter. You could take the bottom filter and put it in a counter that detected radioactive chromium and determine how many cells had migrated into the lower filter. The assay worked and we had a nice publication in the *Journal of Immunology.*

I developed more assays for chemotaxis, and then we got interested in other things the cells did. At this point, my first fellow, Dan Wright [Dr. Daniel G. Wright], worked with me. He and I used a skin blister assay to assess neutrophils accumulating in the skin, a model of abscess formation. We saw some dramatic differences between peripheral blood and skin blister neutrophils. Neutrophils secreted some of their granules as they moved out from capillaries into the skin. We learned that neutrophil granules, the primary and secondary granules, were released in an orderly fashion as neutrophils migrated *in vivo* and these played an important role regulating inflammation. So I became interested in the regulation of inflammation.

At the same time, we started looking at our patients who were on the ward who had recurring infections. We identified patients whose cells didn't work right, and we began to understand the phenomenon of what was abnormal. One of the people I worked with during my second and third year as another fellow from the National Cancer Institute, Harry Malech [Dr. Harry L. Malech]. Harry and I worked together using the electron microscope in Alan Rosenthal's laboratory. We described how cells orient when they're undergoing chemotaxis and we described the critical importance of the cytoskeleton of the cell, especially the centriole and associated microtubules in maintaining the direction of the migrating cell. We were very proud of this and had a paper in the *Journal of Cell Biology*, which was later selected as one of their classics. After his NCI [National Cancer Institute] fellowship, Harry left NIH and went to Yale. Then I recruited him back to NIAID when I was here as a senior investigator. Together we defined the genetic basis of several forms of chronic granulomatous disease and had several papers in *Science* on this topic. Today Harry is leading much of the NIAID gene therapy for children with defective phagocyte function.

Harden: In 1974, you went back to NYU-Bellevue as Senior Chief Medical resident for one year. Tell me why you did this and how you maintained your appointment as an instructor after coming back to NIH.

Gallin: I left NIH because I wanted to get another year of active clinical training and to be introduced to managing a large hospital environment. It was a big honor to be asked to be senior chief resident at Bellevue. I didn't know if I wanted to stay at NIH at the time. My wife really liked New York City, and she missed it. Our families were there, and so we went back. That's also when I developed a very close relationship with Dr. Saul Farber, Chairman of Medicine at NYU/Bellevue. The year as Chief Resident under Dr. Farber was a wonderful experience, both clinically and as an introduction to the administration of a large clinical department. But around October of my Senior Chief Residency, Dr. Wolff wrote me a letter saying, "We'd like to offer you a permanent job at NIH with all the rights and privileges there unto . . . ," and it was co-signed by him and John Seal [Dr. John R. Seal], the Scientific Director of NIAID at the time.

After consulting with my wife, and NYU colleagues including Saul Farber, Gerald Weissmann and Rochelle Hirschorn [Dr. Rochelle Hirschhorn], Elaine and I decided to come back to NIH. But my year at Bellevue was marvelous because in addition to experiencing a tremendous amount of clinical medicine, it was one of my first opportunities to manage a complex department. As chief resident, I managed the house staff. I had the responsibility to assure patient care was top quality. It was a wonderful privilege to have that opportunity and to learn the complexity of managing a department of medicine in a large city hospital.

Dr. Farber wanted me to stay at NYU and offered me a job, but I chose NIH. Nonetheless, Dr. Farber then gave me a window to return to NYU by making me an instructor in medicine for five years while I was at NIH. He said I could come back anytime in the next five years. He would call me every now and then and ask how I was doing. I chose to stay at NIH, but that's how I became an instructor at Bellevue. I went back to give grand rounds every now and then, and my friendship with Dr. Farber grew, and we became friends until he died.

Harden: When you did return to NIH, you got tenure as a senior investigator, correct?

Gallin: There was no tenure process then. All I got was the letter from Drs. Wolff and Seal saying, "We want to offer you a permanent job"

Harden: Right. Three years later, you became Chief of the Bacterial Diseases Section, and you held that post until you became Director of Intramural Research for NIAID in 1985. During this period, you worked on chronic granulomatous disease (CGD). Tell me about this work and about any particular people you brought into your section during this period.

Gallin: Chronic granulomatous disease (CGD) was one of the diseases that we spent a lot of focus on. Children with this disease have broken neutrophils, and lack an enzyme called NADPH oxidase, now named NOX-2. This enzyme converts oxygen to superoxide anion, which then gets converted by superoxide dismutase to hydrogen peroxide, and then by neutrophil myeloperoxidase to hydrochlorous acid (bleach), and then chlorine. All these products kill bacteria. If you do not have NADPH oxidase you cannot make them or make them poorly, and you are susceptible to infection.

CGD was first well described by Charles Janeway [Dr. Charles A. Janeway, Jr.] at Yale and then named by Robert Good [Dr. Robert A. Good], who was a famous immunologist, when he was in Minnesota. He called it "fatal granulomatous disease of childhood." One of his fellows, Paul Quie [Dr. Paul G. Quie], whom I became friendly with, said, "I couldn't tell mothers that their child had fatal granulomatous disease" So Dr. Quie renamed it "chronic granulomatous disease." We became interested in this disease and we started seeing a lot of patients at the NIH Clinical Center, more than anywhere else in the world.

What we realized is that the enzyme that was broken in CGD was a complicated enzyme. It wasn't one protein, it was five proteins that had to assemble to work, and a genetic mutation in any of those proteins would cause the disease. We described many of these patients clinically, then we described them functionally, and then we described them genetically. It was during that time that I recruited Harry Malech and Karen Lomax [Dr. Karen Lomax], Tom Leto [Dr. Thomas L. Leto] from Yale, along with Julie Metcalf [Julia A. Metcalf], a technician who then stayed at NIAID for her wonderful career. We began to study what was really wrong with those patients, and we described the genetics of two of the defects of these patients. We had a series of papers in *Scienc e.* It was very exciting—one great observation after another.

Anther wonderful fellow in my lab was Mark Klempner [Dr. Mark S. Klempner]. He later joined Dr. Wolff when he went to Tufts. Mark is now the Executive Vice Chancellor of Mass Biologics and a professor of medicine at the University of Massachusetts.

Phil Murphy [Dr. Philip M. Murphy] also joined my lab. He is now chief of the Laboratory of Molecular Immunology at NIAID. He worked on chemokine receptors (CCR) on neutrophils. He would number them one, two, three, four, five as he discovered them. As I recall CCR-4 and CCR-5 were a particular challenge to understand functionally. I recommended Phil put them in the freezer until a later date. About eight or nine months later, Bernie Moss [Dr. Bernard Moss], who was a lab chief and well-known virologist in the institute, called me and asked if I knew anyone expert in chemokines and chemoattractants? I said, "Yes, there's this young guy named Phil Murphy." He said Ed Berger [Dr. Edward Berger], who worked in his laboratory, believed he had the co-receptor for HIV, possibly a chemokine receptor. Phil and Ed got together, and in literally in weeks, they had enough data to publish in *Science* and describe the co-receptor for HIV.

Harden: Speaking of HIV/AIDS, before we move forward in time, I would like to drop back to the 1980s. In 1981, NIH began to see patients with what we then just called AIDS. Would you talk about how intramural NIAID responded to AIDS, especially after you became scientific director in 1985?

Gallin: My perspective: I had the laboratory across the hall from Tony Fauci. One day, a CDC [Centers for Disease Control and Prevention] publication called *Morbidity and Mortality Weekly Reports*, or *MMWR*, came out, describing a new illness in homosexual men who were infected with *Pneumocystis carinii*, a microorganism, usually seen in severely immunocompromised patients. Tony and I talked about it. Tony predicted, "This could be really important." Soon thereafter, several other reports appeared describing a similar clinical presentation in patients from California and New York. Tony recognized that this was a disease aligned to his research. He shifted his research direction quickly to study this new disease. There was some fear at NIH that seeing these patients with what became known as the Acquired Immunodeficiency Syndrome (AIDS), a term coined by Dr. Fauci, was too risky. But Tony Fauci took a leadership role for the NIH Clinical Center's studies of AIDS. Soon thereafter the first treatments for AIDS came from NIH and the investigators at the Clinical Center became recognized as leaders in the field.

Harden: Here I want to note that in 1993, I interviewed you in depth about AIDS. That interview is available on the web at https://history.nih.gov/NIHInOwnWords/docs/page_11.html. Also during the early 1980s, there was a major administrative upheaval at NIAID. Dick Krause [Dr. Richard M. Krause] and Ken Sell [Dr. Kenneth Sell] both left NIAID as Director and Intramural Director respectively. Dr. Fauci was then named Director and pretty soon, you were named Scientific Director (Director of Intramural Research). Would you walk me through this transition?

Gallin: Sure. I wasn't Tony's first choice to be Scientific Director. He first asked Bill Paul [Dr. William E. Paul] to be the Scientific Director. Bill Paul, who was one of the great immunologists in the history of NIH, served for about a week and decided he didn't like it, and he stepped down.

Harden: He didn't want it?

Gallin: No. I think it was because at the time he didn't like the impact of administration on his science, but that's my own impression. I never discussed it with Bill. Bill stepped down and said that he wanted to continue doing his job as Chief of the Laboratory of Immunology. Then Tony asked me to do it and I was thrilled to do it. I accepted it. It was about 1985. I did it with the understanding that I could continue my laboratory interests. Tony, who continued his own laboratory interests as Director said, "Fine. Just make sure you balance it right." I spoke to my past mentor, Shelly Wolff, who had left NIH and was now Chair of Medicine at Tufts. He said to me, "Figure out right away what you need in terms of resources for your own science, and never ask for anything else again."

Harden: When you became Scientific Director, you faced the potential for two different kinds of conflict of interest. You had your own lab with you as your own boss, and you also oversaw Dr. Fauci's lab—he was your boss as Director, and you were overseeing his requests for resources. How did you navigate these challenges?

Gallin: We never had an issue because we respected and trusted each other.

Harden: It wouldn't happen today?

Gallin: Today, if you are a Scientific Director, or an Institute Director, your laboratory must be in a different institute.

Harden: When did that start?

Gallin: I can't remember exactly, but about 15 years ago.

Harden: One of your first projects as NIAID Director of Intramural Research was to integrate computers into the functioning of all aspects of NIAID. Tell me about that.

Gallin: That was a great opportunity. When I was a junior scientist at NIAID, I was introduced to and became friends with David Alling [Dr. David W. Alling]. David Alling was a great statistician, and one of the things that made our laboratory so strong back in the 70s and 80s, is that we had a statistician assigned to the laboratory. David was very interested in computers. I can remember we had a Wang computer, which was one of the first computers, but we had it for the whole Laboratory of Clinical Investigation. It was obvious how powerful computers could be to help scientists. When I became Scientific Director, I was lucky in having recruited an outstanding person to work with me as my administrative person, MaryAnne Guerra. We recognized the value of computers early and we recruited Al Graeff (Alan S. Graeff), who later became NIH Chief Information Officer, to put in the first computer network and email at NIAID. We wanted NIAID to be the lead intramural group, one of the first if not the first at NIH to have that capability. We had a great team and successfully built a computer system (email and word processing) that proved very useful to the investigators.

Harden: By the late 1980s and early 1990s, Congress began authorizing a large increase in resources for HIV/AIDS research. Would you walk me through your challenges in scaling up to utilize these increased resources?

Gallin: The first challenge was space. We realized that we were going to be getting more people to work on HIV as Congress began to appropriate funds. We needed more people, and people need space. The first thing Tony Fauci said to me was, "Go find some space." It turned out, after hunting a bit, that there was this wonderful facility up at Twinbrook, in Rockville, Maryland. This was a facility used by the Smithsonian Institution as storage for Revolutionary era furniture. We acquired the Twinbrook facility and identified sufficient funds to renovate the facility into modern research laboratories.

That was the beginning of our expansion, but it soon became clear we needed even more space. Tony became friendly with Senator Weicker [Sen. Lowell P. Weicker, Jr.] from Connecticut. As I recall, Senator Weicker championed the addition of a wing to the Ambulatory Care Research Facility (ACRF), on the east side of the Clinical Center. This new wing for AIDS research was designed to have the glass skin, that I argued strongly was needed to match the ACRF. I also had an office in that facility when it opened.

That's how we got additional space for AIDS research. We also got money to hire people and to build the laboratories. We needed a dedicated AIDS clinic. Dr. Fauci convinced the NIH Director at that time, Dr. Wyngaarden [Dr. James B. Wyngaarden], that we really needed a clinic. The Director of NIH controls all space but rarely exercises that authority. In this case, however, Dr. Wyngaarden cleaned out a whole clinic on the eighth floor of the ACRF and said that this will be a new AIDS clinic. That's how the AIDS clinic, which still exists today, was established.

Harden: In addition to your administrative work during this period, you were winning research awards, and in 1991, were named Chief of the Laboratory of Host Defenses and Chief of a newly created Clinical Pathophysiology section in that laboratory. Can you tell me how you managed to fit into one 24 hour day the administrative demands of being Director of Intramural Research NIAID, the administrative demands of being a laboratory chief, and the research demands of running your section and conducting your own research?

Gallin: I was lucky to have wonderful people working with me. If you ask me, "What do you like best about the NIH?" Highest on my list are the wonderful people who work here. In my research group, I had extraordinary young fellows, three of whom later became lab chiefs: Phil Murphy, Steve Holland [Dr. Steven M. Holland], and Harry Malech.

I had another who became a Division Director in NIAID for the Division of Allergy, Immunology, and Transplantation, Dan Rotrosen [Dr. Daniel Rotrosen]. But there were many more who have gone on to illustrious careers outside NIH. These people made it possible for me to meet with them and to guide them in their research. They were early in their careers, and they had great enthusiasm, so they supported me in doing this. That's how I could do the research. I also had some incredibly wonderful nurses who made it possible for me to continue to see patients. I would never interrupt my clinical care schedule, so I was able to continue to see patients, and that was a great privilege. I spent a lot of time with them. I also had a wife who was phenomenally understanding and supportive and a supportive family.

Harden: Before we stop today, is there anything else that you would like to get on the record about this period before you became Director of the Clinical Center?

Gallin: The only thing I would add is that during this period, I was very attached to the Clinical Center as an entity. I felt that it was an incredibly special resource at the NIH, and I treasured that. I appreciated the relationships that we had with patients. One of the most valuable commodities I felt I had at NIH was time to care for patients. Billing for care was never an issue. All you worried about taking good care of your patients, which included integrating them safely into the research process. You could spend hours with your patients doing good science. The Clinical Center was a special place to work.

Harden: This is a good place to stop today, and we will pick up next week and begin as you become Director of the Clinical Center. Thank you so much.

INTERVIEW 2

This is the continuation of the oral history with Dr. John I. Gallin about his career at the National Institutes of Health, on March 18, 2019, in the NIH Library. The interviewer is Victoria Harden.

Harden: Before we turn to your tenure as Director of the Clinical Center, I believe there were a couple of items that you wanted to get on the record, relating to last week's interview. First, I think there was a childhood experience about a camp you attended. Could you tell me that story?

Gallin: One of the amazing things in my life, when I was a camper for three summers at Camp Tall Timbers in my favorite state, Maine, I was in a bunk with five other campers. We were friends, but after we were 12, we didn't see each other. However, three of us converged as house officers at Bellevue Hospital. We thought that was an incredible coincidence. Then, in early July 1969, we learned each of us would be going to the NIH after our internship and residency. All three of us ended up at NIH pursuing a career of science. One colleague was Harry Greenberg [Dr. Harry B. Greenberg], and the other was Larry Corash [Dr. Laurence M. Corash]. They both ended up in California, having distinguished careers. Harry became Associate Dean for Research at Stanford University, and Larry became Senior Vice President and Chief Medical Officer at company that he co-founded, Cerus Corporation, and we've remained friends ever since. Something in the water in Maine seems to have nurtured young scientists.

Harden: You also wanted to comment a bit more about the people you worked with as Director of Intramural Research at NIAID.

Gallin: Yes. The most precious interactions that I had at NIH have always been with the people I've worked with, and when I was the Scientific Director of NIAID, the people who were my closest mentors, colleagues, were the laboratory chiefs. It was an incredible group. We had six members who were in the National Academy of Sciences, and all you really had to do to be a good Scientific Director was to listen to these people. The lab chiefs were remarkable. They included Bill Paul, Bob Chanock (Dr. Robert M. Chanock,), Frank Neva (Dr. Franklin Neva), Tony Fauci, Bernie Moss, Lou Miller (Dr. Louis Miller) and Mal Martin [Dr. Malcolm A. Martin]. We would meet regularly, weekly or every other week, and discuss their issues. It was a tremendous amount of fun. Very educational for me, and I think the institute did well, because these people were constant advisors and totally dedicated to the success of the institute.

Harden: Let's turn now to your directorship of the NIH Clinical Center. When you became Director in 1994, the post had been headed for four years by Dr. Saul Rosen, but only in an acting capacity. When Dr. Rosen retired, he said in an *NIH Record* article that his overriding goal as acting director was to restore trust in the Clinical Center. Can you tell me how that trust had been eroded and what the situation was when you became Director?

Gallin: There were several issues. One issue related to the funding of the hospital. There had been a lot of strain on funding. There always had been strain on funding since the hospital opened in 1953.

Harden: Why is that?

Gallin: Because people couldn't find the right way to do it. In 1953, it was funded by the number of beds that were assigned to the institutes. At that time, when the hospital opened, there were 500 beds in the clinical center. The Cancer Institute had the most, the Mental Health Institute [National Institute of Mental Health, NIMH] had the second most, and then I think Infectious Diseases [then the National Microbiological Institute, now NIAID] and Heart [then the National Heart Institute; now the National Heart, Lung, and Blood Institute, NHLBI] were right behind them. That was the basis for fees. An institute had an X number of beds, and whether it used them or not, it was charged. A lot of the institutes said, "Well, we're not using all these beds. Why are we getting charged for them?" So that didn't work. After about 10 or 15 years, in the mid1960s and early 1970s, the NIH decided to take new approaches to funding, and the first approach was a fee-for-service model.

In the fee-for-service model, whatever an institute used, it paid for. The problem with that was that it wasn't stable. It varied from year to year, and people thought that wasn't fair. In 1983, I was asked by the then Director of NIH, Dr. Bernadine Healy--when I was the Scientific Director of the Allergy and Infectious Disease Institute--to chair a committee that was going to look into the funding situation. At that point, we said there should be a hybrid system, using a quarterly assessment of use plus some fixed costs based on how much space was assigned to an institute. That worked until funding got tight. When funding got tight, people stopped using the hospital to save money. There was a real concern that we wouldn't keep the hospital patient census up to a critical level needed to keep the hospital afloat.

Harden: When you say people, you mean the institutes?

Gallin: The institutes. Correct. And so, several years later I was asked again by Director of NIH to chair another committee looking at the funding model, and we came up with the idea that there would be fixed and variable costs to the hospital. But as this went on, there was still tension between the institutes and the hospital. The institutes always felt that it was too expensive and the hospital always felt, "We're taking care of sick patients. They're the most precious commodity on this campus, and we can't be cheap. We have to put money into this endeavor." And so that tension always existed. Now, when Saul Rosen was the Acting Director, he had to deal with that tension, and on top of that, there was a very serious adverse event associated with one of the protocols.

Today that serious adverse event is called the FIAU Disaster. FIAU [fialuridine] was a promising drug being used in a clinical trial for treating and curing hepatitis B. The pre-clinical studies, which were led by the late Steve Straus [Dr. Stephen E. Straus], and by Jay Hoofnagle [Dr. Jay H. Hoofnagle], used the woodchuck as the animal model to test this drug, FIAU. In the woodchuck, it worked. Before the animals got better, they had an increase in their liver function tests and that was felt to be due to the fact that the virus was being killed in the liver and the function test went up as if the liver was in trouble. They didn't use any other animal model, and when they went into human trials, there was a disaster. They initially saw the same increase in liver functions that the woodchuck had, but those functions just kept going up and up and up, and to make a long story short, the drug was killing liver cells, and it was killing mitochondria. A number of patients died, and a number of other patients had to have liver transplants on an emergency basis.

That created a lot of distrust in the public, the congressional community, the scientific community, and the community at NIH. It led to a review by the Institute of Medicine; it led to a review by the Congress; and it led to other reviews. The outcome of all these reviews was that this was just the risk of doing clinical research, and that nothing was done wrong by the investigators. In retrospect, if they had also tested a monkey model, they would have seen what they saw in the patients. But that was not done back then.

So it was in that environment that Saul Rosen was Acting Director of the Clinical Center. It was a stressful time for the Clinical Center and for him.

Harden: Is that why no permanent director was appointed in those four years?

Gallin: I do not know the actual politics behind that. I know that he told me he did not have a meaningful relationship with the then Director of NIH, Dr. Bernadine Healy.

Harden: Let's move into the process of how you became Director of the Clinical Center and NIH Associate Director for Clinical Research. I'm wondering things like what kind of search committee was created? Who was on it? I presume you had to apply for the position. What sort of procedure was involved? Who were other candidates, and was there any DHHS involvement? Would you walk me through the whole process?

Gallin: Let me give you a little bit of history. I'm the only person, I believe, who has ever been appointed by two NIH Directors to be the Director of the Clinical Center. When Bernadine Healy was the Director of NIH, she decided to replace the NIH Deputy Director for Intramural Research, who was Dr. Ed Rall [Dr. Joseph E. Rall]. After he was fired, she announced that she was going to hire a new NIH Deputy Director, and Dr. Lance Liota [Dr. Lance A. Liotta] and I were the two finalists. She picked Dr. Liotta. As a side note, in that process, one of the things I did was to recommend that the *NIH Catalyst* be created as a newsletter about research for the intramural community. She liked that idea, and when Dr. Liotta was appointed as Deputy Director, he asked me to be the editor of the *Catalyst*, and I've been an editor ever since. That's been fun.

At the end of Dr. Healy's term, which was two or so years later, she asked me if I would be the Director of the Clinical Center. There was no search. I said, "Can you really do that? You're at the end of your term as NIH Director. There's a change of presidential administrations. President Bill Clinton is coming in." She said, "Yes, I can do it. Will you accept?" And I said, "I'd be honored."

But soon thereafter, the next NIH Director, Dr. Harold Varmus's [Dr. Harold Varmus] arrived. Dr. Varmus decided he would have to conduct his own search for the next Director of the Clinical Center. So Dr. Varmus, when he first arrived, met with me and said it had been a flawed search that Dr. Healy did and that he would not accept it. He was going to start a new search, and he did. Dr. Ruth Kirschstein chaired the search committee. About nine months to a year later, Dr. Varmus offered me the job. I was pleased to accept.

My mentor, Dr. Sheldon Wolff, who at that time had left NIH, asked me, "Why would you want to be the Director of the Clinical Center? You don't have any of your own resources like the other institute directors. You're going to find tremendous tension. It's going to be hard to please anybody. Why would you want to do that?" And I said, "Well, I like clinical research. I believe in it. I believe if I can make a contribution, that's what I want to do."

Harden: You took over from a distinguished line of predecessors anchored by Jack Masur [Dr. Jack Masur], who famously stated about the Clinical Center, "This institution doesn't follow standards, it sets them." What was your vision when you took over?

Gallin: I had some experience with the budget issues, having served on two committees for the NIH Director. I was very interested in stabilizing the budget. I was also very interested in bringing the hospital up to standards with a new building. I thought the building was falling apart in the sense that it couldn't support the modern science that was needed and that it had problems supporting some of the new technologies the patients needed. So, I mentioned this to Dr. Varmus at my interviews, that I was going to be an annoyance and an advocate for this new building. He already had that interest, so he, too, was ready to champion the need for the new hospital. I was concerned about the personnel system in the hospital. It was hard to hire people quickly that we needed, such as nurses and some scarce specialty physicians such as radiologists, anesthesiologists and critical care medicine physicians. The pay scale was too low and the hiring process was too slow. I thought that we needed better strategic planning on an annual basis to understand where we wanted to go. If we didn't know where we were going, I knew we weren't going to get there. And governance was an issue. We did not have an outside advisory group to help us look at the Clinical Center in the context of the rest of the hospitals in the country. I wanted an advisory group. That was my vision, and it happened with the support of the Director of NIH and the DHHS Secretary Donna Shalala as we began to think about the new Mark O. Hatfield Clinical Research Center.

Harden: Before we get to the Hatfield Center, I would like you to explain a little more about how the Clinical Center functions. You talked about personnel like nurses, for whom you would be directly responsible, but I think that directing the Clinical Center is much like directing NIH itself in that you have only so much control over what happens because of the power and funding sources of individual institutes. They control so much of the work that gets done. Would you explain exactly how this works? Are you first among equals as the director of NIH sometimes says he or she is? And how do you navigate the problems?

Gallin: The NIH Clinical Center is an interesting entity. It's the hospital that enables the clinical research science of the institutes. In many respects being Director of the Clinical Center was like being director of a hospital where you had 17 different university presidents that you had to cater to. Only 17 of the 27 NIH institutes used the hospital, but every one of them felt they were paying for it and they had a right to have everything done when they wanted it done and the way they wanted it done. So that was an enormous challenge, and it reached deep into the institution.

The Clinical Center was a hospital in which the hospital did not oversee all the functions in the hospital. For example, the Anatomic Pathology Department, which is a critical department in any hospital in the United States, was run by the Cancer Institute for historical reasons. I had to come up with systems to bring these diverse ownerships together. There were too many silos. One of my goals early on, when I realized that there were 17 silos, was to condense them into one silo, the hospital. So, one of the challenges was, how am I going to do that? How can we change from having five or six different surgery departments? How can we change from having three or four different bone marrow transplant units? How am I going to bring together all these different institutes and make them actually want to work together? My hope was that if I could do that, patient care would improve, collaborations would happen that people hadn't realized might happen, and the science would become even more robust than it had already been.

Harden: One of the first things you did when you became Director was to establish the Clinical Center's Board of Scientific Counselors with the goal, and I'm quoting, "Of taking the research of the Clinical Center investigators out of the closet." Will you tell me about this? What was the situation before you arrived? And how did establishing this board change it?

Gallin: One of the first things I did when I became Director was to go around and talk to the department heads and to people I knew were doing science as Clinical Center employees, not institute employees. Every one of them said, "I don't do science." I said, when I got to Harvey Alter [Dr. Harvey J. Alter], who later won a Lasker Award, I said, "Come on Harvey, I know you do science." And he said, "Well, we're scared to admit it, because we think our job in the Clinical Center is to just serve the needs of the patients directly and to enable the science of the institutes." I said, "But it doesn't make sense, because to get people of outstanding caliber here, we need to offer them the opportunity to do the science, just like the institutes do." Harvey Alter agreed, and so I went to Harold Varmus and said, "Harold, we've got to take the science out of the closet. We've got to admit that we're doing it. We need to create some stable money." He and I agreed this should happen and we set the research budget within the hospital at three to five percent of the Clinical Center budget, no more. The first thing he said, "You must create a Board of Scientific Counselors just like the institutes have to assure the quality of the science is as good as it can be."

Harden: How many investigators at that time doing clinical research were in the Clinical Center?

Gallin: At that time, it was probably about 16, today it's about 22.

Harden: Can you give me a few names besides Dr. Alter?

Gallin: Well, Henry Masur [Dr. Henry Masur], and he has six or seven other “hot shot” investigators in the Critical Care Medicine Department. Tom Fleisher [Dr. Thomas A. Fleisher], who was in the Department of Laboratory Medicine, is another. There were a bunch of other folks who were doing science in the different departments. Lynn Gerber [Dr. Lynn Gerber] was in rehab medicine, and one of the people whom I recruited early on was Zeke Emmanuel [Dr. Ezekiel J. Emanuel] to run the Bioethics Department.

Harden: In 1996, you were elected to the Institute of Medicine of the National Academy of Sciences [now the National Academy of Medicine] for the contributions that you had already made. In the same year you created this Bioethics Department in the Clinical Center and recruited Zeke Emanuel to run it. Tell me why you did that and how it all worked out.

Gallin: The Clinical Center had a long history in ethics. At the second Clinical Center medical board meeting on March 13, 1952, and I quote from the minutes: “The question was raised . . . as to the possibility of the Board’s interest in clinical investigation where hazard to the individual might be involved, and as to whether or not the Board should assume some responsibility regarding policy in this regard.” “…The Committee on Clinical Investigation shall be consulted by any investigator prior to the undertaking of any experimental procedure involving any degree of hazard to a patient. …This committee will advise the Medical Policy Committee as to the advisability of undertaking the investigation in question and the Medical Policy Committee will, in turn, advise the Director NIH, through the Director of the Clinical Center.”

What followed was the NIH “Guiding Principles in Medical Research Involving Humans” which required review by a medical committee of all human research to be conducted at the newly opened NIH Clinical Center. The practice at the Clinical Center played an important role in the writing of the 1962 Kefauver-Harris amendment to the 1938 U.S. Federal Food, Drug, and Cosmetics Act, which stipulated that research subjects must be told whether a drug is being used for investigational purposes and that subject consent must be obtained. In 1966 the U.S. Surgeon General, who was aware of the practice of human subjects’ protection at the Clinical Center, issued a memo to the heads of institutions conducting research with Public Health Service grants requiring prior review of all clinical research, and this became the forerunner of the national IRB [Institutional Review Board] system.

As a clinical investigator, I was acutely aware of the importance of bioethics. I couldn't understand how this institution wouldn't have a very strong bioethics department, given that it was the largest hospital in the world totally dedicated to clinical research. And so, I was set on building such a department. Several years before I came, there had been a very small bioethics department comprising Dr. Fletcher [Dr. John C. *Fletcher].* He was terrific, but he left and went to the University of Virginia, where he ran its bioethics department for quite a while.

I was very excited about building a new bioethics department. The director of NIH (Dr. Varmus) gave me his support and we did a search and I was thrilled when Dr. Emanuel rose to the top of the applicant pool. He was at Harvard at the time. He was trained at Amherst College, which was my alma mater. That didn't have anything to do with his selection. He went on to Oxford after college and studied chemistry. Then he went to Harvard and he worked at the Kennedy School and got a PhD in Philosophy while he was in medical school. He ended up becoming an oncologist but one with an ethics background. I thought he was perfect. He said he would come, but he wanted a year to pull things together and I said, "A year? Okay, no problem. We'll wait a year for you." We did that, and when he came, he asked, "What do I have to do to do a good job?" I said, "All you have to do is build the best bioethics department in the world." And I think he did it.

Harden: It certainly has an excellent reputation. In 1999, you established a Patient Advisory Group to advise on patient care issues. Why did you do this and how has it affected research and patient care?

Gallin: I had the privilege of caring for a lot of sick patients, and I realized very early on that you learn a phenomenal amount by just listening to the patients. Initially, I created this advisory group to advise on the hospital and on operations. We asked each institute to nominate one or two patients to serve on the initial advisory group. We brought them here and they were wonderful. They would tell me what was wrong with the place from their perspective. I used to dread going into the meetings because I knew they were going to say this is bad, that is bad, but when I left the meeting, I was always very excited, because we had a chance to do some new good things. We always tried to respond to what they recommended. Over time they began to have confidence in us, because we listened. The very first thing that they told me--it made a vivid impression on me--was about the speed bumps in the parking garage. They said, "Do you know what it's like to go over a speed bump right after you've had chemotherapy? You vomit. It's terrible." So, within 24 hours, we had those speed bumps taken out of the garage. That was just the beginning of the kind of things that they would share with us.

Over time the patients pointed out that they could also advise on the research. And they said, "Who is better equipped to tell you what the outcomes should really be on a study than the patients?" I listened to them. Let me give an early example of how working with patients can be important in designing a clinical trial. One of my early studies in chronic granulomatous disease was with a new drug, interferon gamma, to potentially treat patients. It was quite clear from talking to the patients that all they cared about was whether we could modify their disease so they didn't have to come to the hospital every few months with an infection. They didn't care about fixing a biochemical defect, they wanted a clinical outcome that would improve the quality of their lives.

Inteferon gamma was owned at the time by Genentech. I contacted my friend Ralph Snyderman [Dr. Ralph Snyderman] who oversaw clinical research at Genentech, Inc. He convened a meeting of about 125 investigators from around the world to consider doing a study, and they all wanted to use the biochemical test as the end point. I said, "No. I won't participate unless the end point is the number of infections." Since I had two thirds of the patients, in the world, I had a lot of control. That's what we did. The study was stopped early, after eight months, by the Data Safety Monitoring Board because interferon gamma was so effective clinically in reducing infections. There was no significant impact on the biochemical abnormality, probably because of variable testing in different laboratories. The patients were right in identifying the best end point. The drug was licensed very quickly by the FDA. The Clinical Center's patient advisory group became advisory not just to how to run the hospital but also how to provide valuable insight in clinical protocol design. In a recent policy I wrote with the current director of NIH, Francis Collins [Dr. Francis S. Collins], on how to do scientific review of clinical protocols, we put patient engagement as one of the requirements for the scientific review of all protocols at NIH.

Harden: In 1999, you instituted something that had never before been done. You permitted extramural researchers to work with investigators through the Bench to Bedside Awards. How did this work?

Gallin: In 1996, we had a little left over money at the end of the year in the hospital, and rather than giving it back to the U.S. Treasury Department, I went to Harold Varmus, who was still the Director of NIH, and asked, "How about creating a new award that we could call the Bench to Bedside Award?" The idea was that we would create a new partnership between a basic scientist and a clinical investigator to do something new. It would seed a new project. The recipients would preferably be two people who are not in the same institute, because I wanted the award to span the silos. He said, "Go for it." I think we had about two million dollars at the end of the year, and we went for it. We got a lot of applications and it was quite popular. Then the next year, I didn't have the money, and Harold said, "I don't have the money, either." So I went "tin cupping" to a bunch of offices at NIH, like the Office of Rare Diseases, the Office of AIDS Research, the Office of Women's Health, and the Office of Research on Minority Health, and they all contributed some money. They would support some of these awards. This way, over a few years, we were able to keep the Bench to Bedside Award program going, and it became increasingly popular and became "official" in 1999. Now, it wasn't until the program had been in place for seven years that one of my advisory board members said, "Why don't you open this up to the extramural community?" So, we did in 2006. It was instantly a very popular partnership. We said that there had to be a partnership between an intramural and extramural investigator to do something that was likely to lead to a clinical protocol that had never been done before. Of the awards given today, 93% are partnerships between intramural and extramural investigators. The awards are relatively small. Today they are $150,000 a year for two years. This is for direct costs, and the money goes to both intramural investigators and extramural investigators. A few years ago, Dr. Collins arranged for us to have some stable money for this program, so I don't have to "tin cup" quite as vigorously as I did in the past. We changed the name of the awards to "Bench to Bedside and Back" to reflect the clinical research cycle of often going from the bench to the patient and then back to the laboratory bench. We now have two and a half million dollars of stable funds, but I still collect from the offices. We now can support about 17 awards a year. It's one of the few ways intramural investigators can supplement the monies that they get for their laboratory. The outcome has been remarkable, with numerous new discoveries, new patents, and new approved drugs and devices.

Harden: You talked about direct funds. Are indirect funds, the overhead costs, factored in?

Gallin: Overhead or indirect costs are provided to the extramural investigators on top of the award. For an extramural investigator to get one of these awards, they have to have an existing grant from NIH. We add the Bench to Beside award funds as a supplement to that grant and indirect costs are also covered.

Harden: I see.

Gallin: Going forward, I would like not to have that requirement for the extramural recipient to already have a grant because I think the Bench to Bedside Awards would also be a perfect award for a very early career investigator, someone who is just starting out. Maybe this could be one of their first awards--a partnership with someone in the intramural program. Currently, the rules are that extramural awardees must have an existing award that can be supplemented.

Harden: Beginning in the year 2000, you oversaw the writing of the pamphlets titled *Standards for Clinical Research* and *Standards for Patient Care*—and then later you updated them. After all these years, why did you need to write these pamphlets ?

Gallin: *Standards of Clinical Research* was written because it was clear that each of the institutes did things differently. Some did clinical research really well and some not so well. I wanted to create expectations across all the institutes that there was a high bar they had to meet. The way we did that was to have the Medical Executive Committee go on a retreat and write these *Standards for Clinical Research*. Scott Whitcup [Dr. Scott Whitcup], founder and CEO of Akrivista, was Chair of the Medical Executive Committee at the time. The Medical Executive Committee had to determine what they thought was required in terms of statistical support, research support, funding regulatory compliance and what resources should be in the office of the Clinical Director versus what should be in each of the laboratories and branches. The outcome of these deliberations was the writing of the *Standards*, and then I said, "Now you have to comply with the standards that you wrote." We set up a process whereby the institutes reviewed each other's performance, and this proved to be a very valuable educational experience.

Harden: Also, that same year, you established the Pain and Palliative Care Service with Dr. Ann Berger as Chief. Tell me why you set this up.

Gallin: It was quite obvious that we were taking care of some of the sickest patients in the world, particularly in the Cancer Institute, but also there were some very ill children with rare diseases. Sadly, some of them died, and at that time, we didn't have a good program, in my opinion, for providing the best care at the end of life. A classmate in medical school, Kathleen Foley [Dr. Kathleen M. Foley], a neurologist who founded and oversaw the palliative care service at Memorial Sloan Kettering Hospital in New York City, advised me on what to try to create. So we conducted a search, and Ann Berger, who had been at Memorial Sloan Kettering when Kathleen was there, was trained as a nurse and then became a physician. After she left Memorial Sloan Kettering, she went to Yale and did some work there. Dr. Berger edited a major textbook on pain and palliative care. We felt extremely lucky that she came here and set up the program. It's had an enormous impact on the quality of life for the patients and their families who need this kind of service.

Harden: And this is for adults and children?

Gallin: Yes.

Harden: Among your clinical center colleagues, you've already mentioned, Dr. Harvey Alter, who worked for many years on what we now call the hepatitis C virus. In 2000 you nominated him for a Lasker Award, which he then received for his work. Could you talk a little bit about Dr. Alter's contributions to protecting the blood supply and use it as an example of how clinical research works?

Gallin: Dr. Alter is one of the most exciting people I have known at the NIH. When he was a fellow here, he worked with Dr. Blumberg [Dr. Baruch Blumberg], who won the Nobel Prize for identifying the hepatitis B virus. Harvey Alter, as a NIH Clinical Associate, was involved with this discovery. The technique used involved an Ouchterlony plate for detecting an antibody in serum from patients with hepatitis. Dr. Alter was a primary author on the first paper describing hepatitis B, and Dr. Blumberg later won the Nobel Prize for his work on hepatitis. Dr. Alter continued his interest in hepatitis, and after he left NIH as a Clinical Associate, he completed his training in transfusion medicine and blood banking and hematology. He then came back to the NIH as a faculty member in the Clinical Center and did research. He set up the Infectious Disease Section within the Department of Transfusion Medicine.

Dr. Alter's goal was to improve the quality of blood given to patients by reducing infectious agents in the blood supply. He is responsible for making our blood supply safe against hepatitis and AIDS. He won the Lasker Award in 2000 for his incredible contributions.

Harden: In June 2001, you were named Physician Executive of the Year for your leadership in the efforts to revitalize the NIH clinical care research program. In light of this, would you give an overview of how things changed in the seven years you had been director?

Gallin: Well, by 2001, we had improved the science being done by investigators employed by the Clinical Center by creating the Board of Scientific Counselors and getting stable funding level for the science of these investigators. Providing stable funds improved physician recruitment and retention of leadership of the clinical departments to the Clinical Center. We improved the ability of our scientists to collaborate through the bench to bedside awards. In addition, improving strategic planning for and the governance of the Clinical Center helped set good direction for activities.

Another thing that I was particularly excited about was our contribution to training clinical investigators. We created a curriculum in clinical research training that had three courses. It started with an introductory course that I led, a seminar group of 15 students in the old Clinical Center building. We met twice a week. Then I began to call on faculty from the NIH to give lectures. To make a long story short, that course grew, and we started having 100 and then several hundred people attend. We filled the auditorium, the Lipsett Amphitheater, every year. Then we got requests to train beyond the NIH, and so, we created long distance learning.

The second course we initiated was set up by Dr. Emmanuel, on the ethical, legal, and social issues associated with clinical research. It became very popular. The third course was a clinical pharmacology course, which I felt was a dying subspecialty because departments of clinical pharmacology and pharmacology were disappearing from American medical schools. We wanted to rejuvenate clinicians understanding of pharmacology. I recruited Art Atkinson [Dr. Arthur J. Atkinson, Jr.], who had been chair of pharmacology at Northwestern University and then went to Upjohn Company as corporate vice president for clinical development and medical affairs. When he retired from Upjohn, he came here and set up this course.

When we were in China, they were very interested in having a broader audience than we could do with just the classroom. And so they initiated long distance learning, and I can still remember flying to about five different cities in China during a course to see how well it worked. The Chinese Academy of Medical Sciences and the Chinese Academy of Engineering were intrigued by this and invited me to co-chair a symposium on translational medicine that's been held every other year. I go there and help organize these international symposia, plan the agenda and participate in the sessions.

When we visit other countries, we put politics aside. We have worked with Roger Glass [Dr. Roger I. Glass], who directs the Fogarty International Center, in helping to identify places to go. We also work with Gray Handley (F. Gray Handley, MSPH), NIAID Associate Director for International Research Affairs, who coordinates a lot of international activity in many countries. We train the people who are doing these studies to help them make sure they're doing them properly.

In sum, I think the change in clinical research at the Clinical Center from 1994 to 2001 reflected a collection of different approaches to operations, management, science and training.

Harden: One thing that I heard you say earlier about when you first became director had to do with the fact that the physical plants of the Warren Grant Magnuson building--the original Clinical Center building--and the ACRF were not in as good condition as you'd liked them to be. That brings us to the creation of the entirely new hospital. The Mark O. Hatfield Clinical Research Center. Would you begin by giving me some background about how this new center came to be: who pushed for it to get DHSS approval, who pushed for it in Congress, and what rationale was used to get Congress to approve it?

Gallin: The most important NIH person who championed this new building was Harold Varmus. He really believed that this was the right thing to do. Other NIH directors before him had said, "Well it's not the right time." He said, "This *is* the time to do it." So he was the real champion, and I shared my thoughts with him about how a new hospital should be designed. He seemed to like these ideas, and he brought me to meet with DHHS Secretary Donna Shalala. It was an interesting meeting. She said, "Well, how do I know this place is any good?" She said that one of her staff had recommended that the Clinical Center be contracted out, and she asked, "Why should we keep it?" I told her why I thought it was important. She said, "I think I'm going to convene a committee to review what you've got out there at NIH." She convened what was called the "Options Team." She asked Helen Smits [Dr. Helen Smits], who was then Deputy Administrator of HCFA [Health Care Finance Administration, now the Centers for Medicare and Medicaid Services], to chair this committee.

Helen came out, and I was quite nervous because who knew what she would think, but she really put herself into our culture and learned about this hospital. She then convened a committee of outstanding hospital executives and people who knew clinical research to form the Options Team. They reviewed us and finally published a book called *The Options Team Report*, in which they recommended building a new hospital.

Then we reconvened with Secretary Shalala, with Helen Smits, and Harold Varmus. Secretary Shalala started going over the report, and she said, "There are several things in this report that you have advocated. One is a new hospital, another is a new personnel system, another is strategic planning, and a fourth is new governance." She said, "We're going to do it all." Then she asked, "Why do you need a new personnel system?" I told her how awkward the current personnel system was with respect to hiring needed people quickly, and she said, "Okay we're going to create a personnel system so you can hire people, nurses, quickly." I said that I also needed to be able to set the salaries each year, based on careful analysis of the healthcare environment in order to get the most qualified people. And so she said, "Okay."

She created a pilot system, a 10-year pilot personnel system called Title 42. I believe that's when Title 42 was brought to the NIH. We were given this incredible opportunity, and it worked. Every year I evaluated the salary structure across the local region and recommended updated salaries based on the competition. They were reviewed by the office of the secretary and approved. That new system worked.

Secretary Shalala then said, "You need a board of governors, and we're going to create a board of governors." She identified John Finan [John J. Finan, Jr.] from Louisiana to be the first chair. He was terrific. Lots of Who's Who from around the United States were on this board of governors named the NIH Advisory Board for Clinical Research. They came twice a year and met with me and discussed how we were doing and what was needed. One of the things we created were operational reviews of each department in the Clinical Center. These reviews were not of their science but for how well we were operating as a hospital. We would convene teams for these reviews so that every four years, each department would get a critical review, and then it would be presented to this board.

The Secretary also said that we should do strategic planning, and under this board, annual strategic plans were developed. To do that, we met with each institute annually and discussed where they had been and where they were going. From collating that data from across all the institutes, we created a strategic plan, which the institutes, of course, had helped to create, so they owned the plan along with the Clinical Center. Again, that helped to knock down some of the silos.

The new building was actually the centerpiece of all this. Dr. Varmus, through his personal lobbying, included me at some Congressional hearings where the new hospital was discussed. One of the wonderful times in my life at NIH was going to these hearings and sitting next to Harold Varmus while we were being questioned about the Clinical Center. The end result was that Congress was supportive.

There was one remarkable day at the Clinical Center while this was all happening. President Clinton came on a Saturday (August 5, 1995) to give a radio address at the Children's Inn. After his address, he came to the Clinical Center for a show and tell. I remember that he was up on the 14th floor of the Clinical Center for the presentation. I was asked to escort the President down a stairwell, in the old hospital, down to the 11th floor to go on clinical rounds. It was just the two of us. So, what do you say to the President when you're alone with him? No Secret Service. As we got about half way down, I had enough courage to say, "Mr. President, this looks like a great hospital, doesn't it?" He said, "Oh, yes. It's wonderful. Everything is great." I said, "Well, it's falling apart, and we need a new building." He stopped and said, "What are you talking about?" So I gave him my 30 second spiel and then we went on rounds.

Who knows what influenced Clinton to support us? It was probably Secretary Shalala, but maybe my little spiel had something to do with it. Soon thereafter the President signed off on moving forward with the new Clinical Center.

Harden: Do you remember any of the particular questions that Congress asked in the hearing you attended?

Gallin: They wanted to know why we needed a new building. What was wrong with the old building? We were able to give, I think, a compelling set of answers, as what we wanted to do in terms of the kinds of research and the kinds of patients and how you couldn't do it unless you had the best facility in the world to do these things. We told them that we wanted this Clinical Center to be a national hospital. Not just for patients--it had always been a national hospital for patients--but also to be a national hospital for investigators. They resonated with that. And they wanted it to be one of the best places in the world. One of the things that NIH has done has been to make the Clinical Center a window to the NIH for Congress. Often, Congresspersons, people from the House and people from the Senate, come on tours. I had the great privilege to be involved in these tours, and we did our homework before they arrived. We would find out what diseases were in the families of each of the people coming for a tour and we would tell them what we were doing related to that disease. That way they understood what we were doing, and they became passionate about supporting us. We never had a visitor here who didn't relate to our mission and want to help.

Harden: Who was involved in getting the Hatfield Center named after senator Mark O. Hatfield? The actual public law is written in the passive voice--it was so named--and it doesn't give any details. Do you know? I know he was chair of the Senate Appropriations Committee.

Gallin: Senator Hatfield was beloved in a bipartisan way. Actually, during the construction of the building, he was remarkable. I can tell you that John Porter [Rep. John E. Porter], who chaired the House Appropriations Committee at that time and with whom I have become friendly, and Senator Inouye [Sen. Daniel K. Inouye] from Hawaii, were very close to Senator Hatfield, and very interested in having the new hospital named after him because Senator Hatfield had been dedicated to clinical research on a national basis when he was in the Senate. I assume, but I don't know for sure, it was Senator Hatfield’s close friends and incredible bipartisan support that got this building named for him.

Harden: Let's move to the 1997 ground breaking. I have a photo here of the people cutting the ribbon. Would you tell me who they all are?

Gallin: The groundbreaking was obviously an exciting moment. In the center of this picture is the Director of NIH, Harold Varmus. To his right is Senator Hatfield, I'm to the right of Senator Hatfield, Senator Spector [Sen. Arlen Specter] is to the right of me. To the left of Harold Varmus was Vice President Al Gore [Vice President Albert A. Gore, Jr.]. Next to him is Secretary Donna Shalala, and next to her is Rep. John Porter, and on the far left is another patient.

Harden: There were seven years of construction before the dedication ceremony in 2004. We'll come back and talk about the construction, but at the 2004 ceremony, of which I also have a picture, the new Hatfield Center became known as the “House of Hope.” Can you tell me how that came about?

Gallin: At the ribbon cutting ceremony, I wanted to have a patient as one of the featured speakers. We had all sorts of fancy people on the podium who spoke. The patient who spoke, Susan Butler, gave a compelling talk, maybe the best talk of the event. In that presentation she called the Clinical Center the “House of Hope.” Susan had had breast cancer two times and ovarian cancer. She was a real advocate for supporting cancer research. She told her story that you never know whether you're going to be here tomorrow when you have what I have, but this place was extraordinarily important to her. I never forgot her words. In fact, we have a little plaque and a picture of her on the wall outside our patient activities room in the hospital, recognizing what she did on that day. Francis Collins caught on very quickly to this idea of hope. He liked it. He actually says it was my idea, but it wasn't mine. It was Susan Butler’s. Francis developed a pin, a lapel pin. He likes to play the guitar, and so he modeled guitar pick into a lapel pin that says, “Hope at NIH.”

Harden: Let's now move back to the design of the new Clinical Center. I want you to tell me about the architect and what involvement you might have had in the way it was designed. I have always been fascinated with the design of the atrium.

Gallin: The identification of the architect was a very exciting period. We decided to do, for selection of the architect, what NIH does so well for grant proposals. We had a competition. The architecture world had never seen anything quite like what we did. We put out a request for applications and we received applications for this hospital from the very best architects in the world. Really, the very best. We had a team put in place to review these applications. I was lucky to sit on this team. We brought all the architects to the NIH to outline what we wanted. I remember clearly saying to them, "We want the capacity to change. That's the most important thing. We know that the changing science is going to mean a changing building. So, we want a flexible building that we can modify as time goes on. How do we do that?"

They all submitted their submissions, and these were very beautiful books. Then we decided to have a poster session in which they would put their ideas on a poster, just like a scientific presentation. We took over Wilson Hall in Building One. We had all the posters displayed, and we invited the NIH community to come and view them. We gave out score sheets and asked the members of the NIH community who came to grade each submission. This way, the entire NIH community had an opportunity to rate all the architects. There's still a book of scores and comments by the NIH community. I'll give you an idea of which architects competed and what they offered. First was Renzo Piano from Italy, who designed the Centre Georges Pompidou Museum in Paris and received the Pritzker Architectural Prize (1998), which is like the Pulitzer Prize for architects. He submitted a proposal in which he said, “Your old hospital is so ugly, I want to wipe out the entire ground floor so it will be a see-through space.” He said, “It's going to be terrific.” I asked, “How much is it going to cost?” And he said, “If cost is an issue, you don't want me.” We obviously did not choose him.

The person and firm that was most compelling for meeting the need for a flexible building that could adapt to future changing scientific and clinical needs was Zimmer Gunsel Frasca (ZGF) Architects, headquartered in Portland, Oregon. It's coincidental that it's in the home state of Senator Hatfield. Bob Frasca [Robert J. Frasca] was the lead architect on the design of this building. He had designed the Fred Hutchinson Cancer Center in Seattle Washington which had many features we were looking for. I had a chance to visit that center and was particularly intrigued by it because it was modeled after the Scripps Clinic, a very famous scientific building, where every other floor is an infrastructure floor. The Fred Hutchinson Cancer Center, I think, was the first research hospital in the world that had that same idea of making every other floor an infrastructure floor. And because every other floor supported infrastructure, you can make changes very easily. We decided that was what we wanted in the Clinical Center. It thus worked out that ZGF Architects was the firm selected, and we have that design, with every other floor being an infrastructure floor. It's been a marvelous design for us.

Now, in a personal aside, during this whole experience, my son was an architecture student, so I had something to talk to him about!

It was very exciting to be Director of the Clinical Center during the design and construction process. In the architecture firm, the lead local person was Margie DeBolt, and she was terrific at bringing together all the different institute representatives from every level in the organization. These ranged from the senior scientists, to the physicians who did not do science, to the nurses, to the house keepers, to the electricians--to everybody. They all played a role. Margie DeBolt had numerous, literally hundreds of meetings with all these people to understand what we needed, and the end result was the design that we have.

The competition among architects we used was actually written up in *Architecture* (M. Bradford, “NIH’s Newest Experiment,” March 1996, pp 131-139) as a unique way to select a firm to do a big building. And now we have this wonderful facility, and it is flexible. For example, between the time the building was designed and when we opened the building, the obesity epidemic hit the country, and it became a huge issue. We were able to modify one of the patient care units even before we opened the new hospital to accommodate morbidly obese patients—patients who weighed up to 600 pounds. We had to change the doors. We had to change the toilets, so they would not hang from walls but rather sit on the floor. We had to change the stretchers, the wheel chairs, the doors, the beds, the operating room tables, and the MRI machines to accommodate the patients. The obesity unit was only a 10 bed unit, yet resulted in huge changes throughout the hospital.

Another unit we had to change occurred when the Ebola crisis emerged. We realized we had to be able to take care of people with extremely high risk, infectious diseases. So, we modified a unit to be able to do that. We continue to modify our units as we need.

Harden: Wow.

Gallin: Let me tell you about the atrium. Originally our architect, Bob Frasca a marvelous idea. He wanted to build two scientific “metaphors,” a double helical staircase in the atrium modeled after DNA and a sky light with two rings of dichroic glass that would cast two color rings on the floor which, depending on the position of the sun during the day, would become coincident, like focusing two rings of a fluorescent microscope.

Harold Varmus saw that plan and said, “Mixed metaphors never work. We can't do that.” But, he liked the double helical staircase. So the plans were drawn to put this staircase in the middle of the atrium, and on each landing of the staircase, we planned to have a quote from a famous scientist. And again, we went to the community and asked them to give us quotes, and a lot were submitted. I went to *Bartlett's Familiar Quotations* to authenticate them. I showed them to Dr. Varmus, but he said, “That's not good enough. How do you know they're really correct? Maybe Bartlett's isn't right.” So he sent me to the Library of Congress to get them authenticated.” I did, and sure enough, some of them were wrong. The plans for the double helical staircase were developed. But then Dr. Varmus left NIH, and Dr. Ruth Kirschstein became the Acting Director of NIH. A cost overrun for the new hospital ensued and Dr. Kirschstein worried about the cost and potentially perceived lavishness of the staircase. So, the double helical staircase got killed.

We were disappointed, but actually it turned out to be good, because the atrium’s wonderful open space is a great gathering space, and it's also a great place to have music. By coincidence, the acoustics are really good, and after the building opened, the National Symphony Orchestra came. They decided that they wanted to launch a “Sound Health” initiative and they wanted to start by playing at the Clinical Center at NIH. We arranged for them to come, and they came with pretty much their entire orchestra. The National Symphony started coming three to four times a year, because no other hospital had a setting quite like NIH. The Sound Health initiative grew and with Dr. Collins’ support a close partnership between the NIH and the Kennedy Center evolved to study the role of music in health care.

Harden: Do the diagonal lines in the atrium have any meaning?

Gallin: They do. Originally, they were going to speak to the double helical staircase, but now they reflect the design in the ceiling. It was all carefully thought through by the architect. Also, the structural supports on the north and south sides of the atrium are an abstract reflection of a double helix structure.

Harden: I was grateful that your sense of medical history led you to have an installation of the medical history art deco panels that were on the main elevators in the original Clinical Center. You enlarged them and had them placed on a wall.

Gallin: Yes. When the first elevators were constructed in the lobby of the original Clinical Center, the stainless-steel elevator doors had engravings telling the story of early medicine. And I always loved them. When I first came here, those elevators provided vertical transportation in the hospital and actually had an elevator operator. As we planned the new building, I was trying to figure out how to get the old building to speak to the new building. One of the things I told the architects is that we needed to bring light down into the garage, and so there was a section in the new building on top of the garage. Bob Frasca put skylights into this space to bring light to the garage to facilitate way finding for patients parking their cars. The walls from the skylights to the garage entrance were long, and I said, "Why don't we make wallpaper out of these elevator images. So the art department in the Clinical Center fell in love with that idea and they made the wall paper which look like large carvings of the original elevator doors."

Harden: It's wall paper? Wow!

Gallin: It looks three dimensional, but it is wall paper.

Harden: It does look three dimensional.

Gallin: It's beautiful wallpaper and it's a replica of these images.

Harden: What else do we need to know about the construction and opening of the Clinical Center before we move on?

Gallin: Well, when we designed the building, we fixed a few serious problems in the old building. I was concerned about vertical transportation and asked Bob Frasca to build extra elevators so we wouldn't have to wait to go up or down and he did that. In the old hospital there were three bone marrow transplant units, but we decided there should be only one bone marrow transplant unit. So, we introduced a "new" word into our culture: "sharing." We told all the institutes they were going to be sharing resources. We said, there's going to be only one bone marrow transplant unit. We said there is no longer going to be two intensive care units, one for medicine and one for surgery. We created a single Critical Care Medicine unit. Decisions like this brought teams together and improved patient care. Very early on as the building was being designed, we set up teams for each patient care unit that would bring the different institute care teams together to figure out how to best manage each unit to provide optimal patient care. These patient care teams, bringing together the different institutes with the Clinical Center nurses, continue today. This has worked very well to improve efficiency, provide better care and enable improved operations for accomplishing clinical protocols.

Harden: So, no longer would you have the situation where the Cancer Institute would have X number of beds, and the Heart Institute would have X number of beds, which they controlled and had to—

Gallin: That's correct. Now, we do have some special clinics, and patient care units for highly specialized needs. For example, a cancer unit for administering chemotherapy is needed, or an obesity unit is needed, or a unit for high containment infectious diseases is needed. But most patient care units now are generic for all institutes who need them and are not "owned" by individual institutes.

Another thing that we have in the hospital which many people don't realize, is a full school that runs from kindergarten through high school. The teachers come from Montgomery County in Maryland under contract. We hire them. We had to figure out where the school was going to be placed.

Harden: This is for pediatric patients?

Gallin: Yes. For pediatric patients. One of our goals was to make sure these children, who often have to stay a long time in the hospital, didn't lose time in school. We're very proud of the fact that this school works. We have a one room schoolhouse adjacent to the pediatric unit, and teachers will also go to the bedside when needed.

Another thing we created in the new hospital, which has also been very successful, is what we call "day hospitals." Day hospitals are places where outpatients can come and spend hours volunteering for study, or patients who have a serious clinical problem can come and get chemotherapy for hours and not have to be in the hospital. We put these day hospitals adjacent to the patient care units so that when patients come back as an outpatient, they already know the team. This improves continuity of care and research protocol oversight as patients move from in-patient to out- patient and vice versa.

Harden: The “day hospitals”--I like the term much better than “ambulatory care research facility”—did they take over what was going on in the old ACRF?

Gallin: No. The day hospitals are for high acuity activity related to care, such as chemotherapy, or complex research protocol activity. The patient may be in the day hospital for 12 hours and we have a mixture of beds and lounge chairs for the patients. The Ambulatory Care Research Facility (ACRF) still exists as a regular clinic often for much shorter patient visits, and it is very actively utilized.

Harden: Paralleling the building and opening of the Hatfield center, was the opening of the Edmond J. Safra Family Lodge, a facility that you conceived, as I understand it. And you also championed fundraising by the Foundation for NIH, the FNIH. Would you tell me about this?

Gallin: The idea of a family lodge came from discussions with our nursing team. At that time, the Chief Nurse, Kathy Montgomery [Kathryn Lothscheutz Montgomery, R.N., Ph.D] and I talked a lot about having a place where patients and families of adult patients could stay. We had a Children's Inn for children and their families. I really liked the idea of a place for adults, like the Children’s Inn. At the time, I was on the Board of the Children's Inn. Now I'm on their Board of Trustees. I asked fellow Board members, “How would you like to change the name of the Children's Inn to the Family Inn?” They smiled but said, "No, thank you. We have a good brand. We don't want to tamper with it. We're not going to do that." I was disappointed, but one of the members of the Board was Mark Raabe [Mark L. Raabe], a lawyer for Merck Pharmaceutical Company, which had very quietly given a lot of the money to help the Children's Inn get built. He said, "I like this idea, let me see what I can do." This was before the Foundation for NIH existed.

Several months later , Mark Raabe came back to me and said, “I'm really disappointed. I can only get you one and a half million dollars from The Merck Company Foundation.” I said, “You're disappointed? What a gift!” Then I said, “But I'm not allowed to raise money. That's against the ethics rules at NIH.” Coincidentally, that is when the Foundation for the NIH started. The first chair of the board of FNIH was Charlie Sanders [Dr. Charles A. Sanders]. Charlie Sanders had retired as CEO of GlaxoSmithKline. He immediately loved the idea of the Family Lodge. He said, “John, we're going to create it. Don't worry about it.” And he went and got gifts from the Bristol-Myers Squibb Foundation and Glaxo Wellcome, Inc. So, then we had had sufficient funds to start the project .

The Foundation for NIH got an architect, Dr. Amy Weinstein of Weinstein Associates Architects, who designed it. But the Family Lodge was going to cost more than we had. Charlie Sanders said, “We'll work on it. Don't worry.” He got another company to give additional support and then, this incredible woman, Lilly Safra, whose husband died away from home, understood what our patients were going through, often being a long distance from their homes. Lilly Safra is a philanthropist who gave the remaining money needed to enable the construction and opening of the Family Lodge, now called the Edmond J. Safra Family Lodge, after her deceased husband. I was lucky to be involved in the conception of the lodge and to work with the architect and the FNIH to design and then build the facility.

This past year, the Lodge needed some face lifting and refurbishing. Lilly Safra provided additional money to refurbish the lodge. Almost every Thanksgiving, my wife, Elaine, and I go there and serve lunch. We were also pleased to be able to purchase a self-playing piano in the Lodge library. We and other members of the NIH community interact with the patients and their families who are staying there. The Lodge is a wonderful addition to support our adult patients and their families.

Harden: How many patients and their families can stay there?

Gallin: The lodge has 34 guest rooms and from 2005 through October 2018 welcomed about 140,000 guests from all 50 states and around the world. In some cases, there are two family members in a room, but you can put three or four. There are some rooms for children and some play areas. The Children's Inn will not accept children who are not patients or siblings of patients but we can at the family lodge. One of the great things that used to happen there was that Marvin Hamlish [Marvin F. Hamlish], a close friend of Lilly Safra who was a great musician and composer, used to come every Christmas to play and bring Kennedy Center performers to perform at this lodge in the living room. This were wonderful events that really brightened the holiday season for the patients and staff. Near the end of Marvin Hamlish's life, I got him to perform in the atrium at the Clinical Center where he could reach a larger audience.

Harden: In 2004, the year the Hatfield Center was dedicated, you established a new hospital electronic medical record called the Clinical Research Information System, CRIS, and in 2009 you oversaw the creation of the Biomedical Translational Information System, BTRIS. The goal was to bring together clinical and basic data on patients to facilitate individual investigator’s projects and data sharing. Tell me about creating these systems, how they work together, and what difference they have made.

Gallin: In the 1970s, the Clinical Center created the first electronic medical record in a research hospital environment. That was when Mortimer B. Lipsett was the director—he served from 1976 to 1982. Dr. Lipsett’s deputy director, Griff Ross [Dr. Griff T. Ross], led the effort to build the first electronic medical record at the Clinical Center, which I believe was the first electronic health record used in a research hospital. Tom Lewis [Dr. Thomas L. Lewis] played a key role designing and building the first system known as the Medical Information System, or MIS. But twenty years later, MIS had become obsolete with all the advances in Information Technology. We needed to create a modern information system to house patient records. I recruited Steve Rosenfeld [Dr. Stephen J. Rosenfeld] to do this. I had some experience with electronic records when I was Scientific Director of NIAID, and I had recruited Al Graeff who later became the first NIH CIO to put in, I believe, the first email system at NIH. Steve Rosenfield had trained as a hematologist and he had a keen interest in IT. He created the new MIS called the Clinical Research Information System or CRIS. That became the electronic medical record. Now, the good thing about CRIS is that you could look at one patient’s record at a time for health care. The bad thing about CRIS is you couldn't look across a cohort of patients who had a particular disease.

Now we had a new need. We wanted to be able to merge clinical information across all the patients in the hospital and we needed to be able to merge the clinical information with related research information generated in the principle investigators' research laboratories. To respond to this need, the Biomedical Translational Research Information System (BTRIS) was conceived. We recruited Jim Cimino [Dr. James Cimino] from Columbia University who was both an internist and an IT expert, to create BTRIS. The goal was that every night, all the hospital data would be deposited into BTRIS, and every day, all the institutes' research information related to the patients would also be put into BTRIS. Since the institutes' research information was housed in different databases, it was necessary for BTRIS to be able to merge the various research databases with the hospital electronic patient record. BTRIS did this and has proven an important tool to facilitate clinical research. It also has become valuable for facilitating certain hospital operations, such as tracking infections across the hospital and adverse events related to clinical research. We see BTRIS as a tool to share clinical research data. As hospital and research data become big data, BTRIS will evolve and NIH policy will develop to enable sharing of data not only across the NIH institutes within the intramural program but between the intramural and extramural partnerships.

Harden: But at the same time, I trust that patient's privacy is completely protected.

Gallin: That's number one. I mean, you always worry about patient privacy when you have any kind of patient information system. Can you really protect privacy? Our CRIS system is not connected to any other system at NIH. It stands alone, so an intruder can't get into it. Now, recently I've become a little nervous because we decided to let the patients access their own records. We've created patient portals, and then we've created portals for their physicians to see the records on their patients.

Harden: When you say their physicians, do you mean physicians outside of NIH?

Gallin: Yes, their private physicians. So, if somebody lives in Alaska and their doctor wants to see their records at NIH, they can do that. You always worry that such access creates a vulnerability. We think we've set it up so that it's secure, but everybody always worries about that.

Harden: In 2011, you accepted the Lasker-Bloomberg Public Service Award on behalf of the Clinical Center, and under your leadership the Clinical Center was the first hospital to receive this award. Can you tell me how this came to be?

Gallin: After Harvey Alter won his Lasker Award, and I had been involved in several other Lasker nominations, I thought, "Why can't the hospital win it for public service?" So, we set out to figure out how to do that. John Porter had just stepped down as the Chair of the House of Representatives Appropriations Committee. He said, "I'm willing to do the nomination. I'll sign it," and former Secretary Department of Health and Human Services, Dona Shalala, who was then president of the University of Miami, said, "I'll write a supporting letter." And Senator Inouye, who was a close friend of Senator Hatfield, said he would also write a letter. All these wonderful people were willing to support the nomination. In addition, we received support from scientists and also patients who contributed letters of support. And so, the nomination package was submitted, but some people said, "You'll never win it. They always want a famous person to get the public service award." I said, "We'll wait and see." And we won! When we received the Lasker Award, I had the privilege of accepting the award on behalf of NIH. It was called the Bloomberg-Lasker Award and Michael R. Bloomberg, who was mayor of New York City at the time, handed me the award along with Maria Freire [Dr. Marie C. Freire], who was president of the Lasker Foundation at that time. She's now president of the Foundation for NIH.

Harden: We will stop here for today. Thank you.

INTERVIEW 3

This is interview three of the oral history interviews with Dr. John I. Gallin about his career at the National Institutes of Health on March 27, 2019. The interviewer is Victoria Harden.

Harden: Dr. Gallin, let's return to our discussion of your tenure as Director of the Clinical Center. In 2010, under the authority of the NIH Reform Act of 2006, an NIH Scientific Management Review Board was created. It was chaired by Norman Augustine [Norman R. Augustine] of Lockheed Corporation. My first question is why a distinguished aeronautical engineer was appointed as the chair of a committee to evaluate the NIH Clinical Center? There was also a former NASA administrator on that board in addition to physicians. Can you tell me why these two men were appointed?

Gallin: This committee reviewed the entire NIH, and one of the pieces of the NIH that they paid some attention to was the Clinical Center. Norman Augustine was selected because he had a record of taking on challenging projects for the government. For example, when the Challenger disaster occurred, he was asked by Congress to review that horrible event and make recommendations to try to reduce the likelihood it would ever happen again. He was felt to be well positioned to take on challenging projects. He had served previously at NIH, helping with some other committees as well.

Harden: He didn't need to know medicine himself then to—?

Gallin: That's correct because he called upon experts to provide advice about the systems we had in place—we needed system engineering advice. And those experts included a lot of outside people. Dr. Gail Casell, who had been involved in one of the early reviews of the NIH, was on that panel, and she had some unique experience looking at clinical research organizations. At that time in her career she was at Eli Lilly, but she had also been in academia, coming out of the University of Alabama. And they called upon some of the NIH directors to serve as advisors on that panel, including Dr. Anthony Fauci and Dr. Stephen Katz.

Harden: In December 2010, the board issued its report on the Clinical Center. Originally, it had focused on the Clinical Center's fiscal constraints, including its inability to keep pace with inflation. But then it also discovered challenges in the areas of the Clinical Center's vision and role at NIH and its governance. Would you tell me about the board's activities in general and its recommendations?

Gallin: The board was very concerned about the funding of the hospital. The hospital lived within the budget of the NIH and therefore was under the same constraints as the whole NIH budget. There was a period of time when NIH really had almost a flat budget, and we were very concerned about that. For a hospital with medical inflation increasing at enormous rates compared to inflation in the rest of the economy, we were put in a situation where we really had to struggle to keep the hospital safe, to keep the research opportunities robust and active in times of financial difficulty. The budget had been based on a school tax levied on all the institutes, who also were under tight fiscal constraints.

Harden: Would you please define “school tax”?

Gallin: Yes. The Advisory Board for Clinical Research, which Donna Shalala had created, came up with the idea that hospitals should be treated like a school library—that is, it's on the campus and you can use it if you want, but regardless you're going to pay for it. Mary Sue Coleman [Dr. Mary Sue Coleman], who at the time was President of the University of Iowa, was on the Board and was the one who conceived of the “school tax” idea to pay for the Clinical Center. Under the “school tax” each institute was tapped to pay for the hospital in proportion to the size of its financial budget. The largest institute, the Cancer Institute, paid about 25% of the cost of the hospital, and other institute taps went down from there. In times of tight budget constraints, this created strain across the entire organization. What the Scientific Management Review Board recommended was that the Clinical Center should have a line item in the NIH budget. That is a budget directly from Congress to the Clinical Center. This was not a novel suggestion. It had been requested as far as I know by every Director of the Clinical Center since it opened.

Giving the Clinical Center a line item in the budget had never been done because there were concerns that it would cause politicization of the hospital and might result in having a “disease of the month” mentality. There was concern that the Congress would say, "We'll give you this money, but you're going to study disease X this year." And we did not want that. That was one of the reasons, and there were other complexities to that proposal, and after a lot of discussion, NIH decided not to pursue a line item budget for the Clinical Center. The hospital continued to be under this school tax funding mechanism, which, during times of budget constraints, created pressure on hospital management to “do more with less.”

Harden: But after this board submitted its report, the line item was enacted correct?

Gallin: No, the line item was rejected, despite a very strong recommendation.

Harden: Even today, the Clinical Center is still funded under the school tax?

Gallin: Correct.

Harden: Would you talk a little more about what this board found about the vision of the Clinical Center and the governance of the Clinical Center, and what its recommendations were related to its findings?

Gallin: Yes. One of their recommendations was that the Clinical Center should be a national research hospital. It had always been a national hospital for patients. But the board said you should open the doors of the hospital to the extramural academic community, and to the outside community of industry, to leverage the strengths of this research hospital, the largest hospital in the world totally dedicated to clinical research, to enable clinical research to occur that might not be possible otherwise. One of their very strong recommendations was to create a new grant mechanism, and that has been implemented. The title of the new grant [designated a U01 grant]was “Collaborative Opportunities at the NIH Clinical Center.” These were large grants of about $500,000 a year. They allowed extramural investigators to partner with people at the Clinical Center to pursue a new research project using the hospital. These grants have now been in place for seven cycles. To date, NIH has funded 35 awards at a half a million dollars a year for five years, and they can be renewed.

Harden: This is broader than the “Bench to Bedside” initiative.

Gallin: This is broader because it's a lot more money, and the extramural investigator is the lead PI [principal investigator]. The monies go to the extramural investigator, they go to the hospital to cover some of the hospital costs, and they go to the intramural investigator.

Harden: If I may just return to the budget for one more question: the Clinical Center was struggling mightily under the funding with the school tax, so if nothing changed, is that still a constant ongoing struggle?

Gallin: Well, there's a tension. There's a tension because you have 17 institutes and centers that use the hospital, and each one of them wants the hospital to do just what they need. But the hospital needs to serve everyone. Each institute director you could think of as a university president, and it's as if we have 17 universities using the hospital, and each university president wants to be in full control. That's obviously impossible. And so to address this problem, one of the recommendations of the Scientific Management Review Board was to continue a governance structure already in place in which some institute directors--not all of them, but the ones appointed by the director of NIH--form a Clinical Center governing board. The Clinical Center governing board has been in place since a little before the Scientific Management Review Board was constituted, and for many years, it was chaired by Dr. Steve Katz until his death in 2018.

Harden: And that has helped?

Gallin: It has helped because the Clinical Center Governing Board understands what the challenges are. They can be very strong advocates for the financial needs of the hospital when needed. But even with them, there is a little bit of a conflict of interest because you have the hospital funding on one hand, which they pay for, and the need to balance Clinical Center funding against the many other programs they support. I personally have always been an advocate for a line item budget, and I have tried that with each director that I have served under, namely, Dr. Harold Varmus, Dr. Elias Zerhouni and currently Dr. Collins, and they've always been intrigued by it, they've all discussed it, they've all brought it to the table, but it's never moved forward.

Harden: Is there anything else about this Scientific Management Review Board that you want to comment on?

Gallin: No, I just think it was very helpful. There were lots of good discussion. I thought that creating the U01 grant was important. We're now trying to identify more ways to open the doors of the hospital to the extramural community. A nice feature about the U01 awards is that recipients of these awards in the extramural community have been located across the country. They've been on the East Coast, the West Coast and in between. Geography has not been a problem in making these awards happen. There was a lot of concern initially that only the local hospitals would want to partner with us. That's not the case. We have some really wonderful partnerships throughout the country.

Harden: Are the extramural PIs who come to use the Clinical Center subject to the same kinds of ethical restrictions that intramural investigators are?

Gallin: That's an important question, and the bottom line is that we require that extramural investigators follow the guidelines of their home institution. And we get that validated. As long as they are following the guidelines of their home institution, they can work here. But they don't provide day to day care of patients. The intramural staff care for these patients. There have not been as many patients brought into the hospital as we would have liked by this grant mechanism. The Bench to Bedside awards, for example, now account for about 4% of the total patient population in the hospital. The Bench to Bedside awards are smaller awards designed to seed new projects between a basic scientist and a clinical investigator. They are only $150,000 a year. Today over 90% of Bench to Bedside Awards are partnerships between intramural and extramural investigators. The U01 grants, which are much bigger, are bringing in less than 1%—actually a fraction of a percent—of the total patient population. Because of this, we have now modified what we call the RFA, the Request for Applications for the U01 grants, to require that the applications state how the extramural collaboration will bring more patients into the hospital.

Harden: In 2016, the Discovery Channel arrived at the Clinical Center to begin work on a documentary produced by John Hoffman that was called *First in Human*. It followed three patients in clinical trials, to show the public how such trials work, and was shown on TV in 2017. Tell me about producing this documentary, what was required from the Clinical Center to provide access, and how the patients reacted and interacted with the Discovery team?

Gallin: This was an exciting project. John Hoffman, the producer, was very engaged. He was supported by the NIH administration because he had helped NIH on some earlier projects that were successful. I can still remember when the Chief of Communications at NIH, John Burklow, called me and said, "Would you guys be interested in working with John Hoffman to create this project?" I said, "Absolutely. We'd like to explore it and find out what it entails." So John Hoffman came here and said his goal was to do only a few things: to get more money for the NIH, to introduce the Clinical Center in a better way to the public, so people would know more about it, and to make it a very positive experience. We said, "We can make it work, but there are certain restrictions. Those include patient confidentiality. We always have to have a team with your reporters and filmmakers to make sure that things are done right."

They said, "Fine." They brought three camera crews here, and they were here every day, seven days a week often more than eight hours per day. And often they had one crew here at night for over a year. They recorded, not three stories, they recorded many, many stories of many patients. And their goal initially was to capture the role of the entire hospital team, from the people who work in the food preparation department, to the people who load or unload things from delivery trucks on the receiving docks to the housekeepers. All these people had wonderful stories to tell because they recognized that for the Clinical Center to be effective everything had to work, it was like a chain--any weak link in the chain and the whole place falls apart. They filmed many, many, many hours.

I had the privilege of working with them on some of those stories, as did my office team. Our communications team accompanied every camera crew. When it was all done, this enormous information collection was reduced to the story of a few different patients. Although the Discovery Channel team decided not to show all the stories they had filmed, they did make them available to us if we thought they might be useful down the road in anyway, because there are some lovely stories in there that were not on television. After they started editing and cutting, they invited a few of us up to New York to participate in the screening and further editing, and then they disappeared, and six months later the program came out. It was a very exciting, and I think it was a special product. A lot of people called and wrote and thanked me. People I knew and people I didn't know.

Harden: I saw it and thought it was brave in that that it did not show consistently happy endings. It was a story about the reality of clinical research.

Gallin: It told a true story. Hospitals are scary places, and people come here often at the worst times of their lives. But we provide hope, and that is special.

Harden: In April 2015, fungal contamination was discovered in vials of albumin being prepared for administration to patients. The albumin was made by the Pharmaceutical Development Section in the Clinical Center. In May the Food and Drug Administration inspected the unit and found a series of deficiencies. This started the ball rolling in what became a major reorganization of the Clinical Center. Can you walk me through all this?

Gallin: In April of 2015 a very alert technician working in the NIH Pharmacy was drawing into a needle some albumin which comes in a vial. Albumin is an important protein that you give sometimes to patients. And she noticed as she was pulling the albumin into the syringe through a needle, there was some resistance. It didn't flow quite the way it should. So she stopped what she was doing, and she squirted the material back into the vial and looked at it, and noticed something white floating in the bottle, and then she did the right thing. She immediately went to her supervisor and said, "I think there's some cotton in here. What do you think?" And the supervisor looked at it and said, "I'm not so sure it's cotton." It wasn't cotton. It turned out to be a fungus. And that fungus was detected before it ever was administered to a patient because of an alert technician. No patient got hurt.

People at that moment acted right. They called the head of that Pharmaceutical Development Section, and then the head of the NIH Pharmacy, and production of albumin was put on hold. But a whistleblower was concerned about Pharmacy operations and called the FDA. In response to that phone call, the Food and Drug Administration came out for an unannounced inspection. At the end of the second day, I was debriefed by the FDA, and because of findings of irregularities in operations of the Pharmaceutical Development Section, I placed the entire section on hold, prohibiting any further product production.

The Pharmaceutical Development Section had been an extremely novel and important part of the research hospital. It's where we could prepare first-in-human products to go into patients. Very few places have that capability. We thought that it was a good team and had had an operational inspection by the NIH Advisory Board on Clinical Research of the entire pharmacy department about a year before the FDA inspection as well as a review by the Joint Commission on Hospital Accreditation. The outside reviewers thought the pharmacy department was good but were concerned about tight budgets, heavy workload, and staffing shortages. Dr. Collins was very concerned about the FDA inspection and decided to do a comprehensive review of the entire Clinical Center. He decided that it was extremely important to be totally transparent, to go to the newspapers and to go to Congress and tell them about this problem.

Congress, Senator Alexander [Sen. Lamar Alexander], I think in particular, said he wanted a review. He had a term for high level reviews of places that had problems, a “Red Team.” And so the Clinical Center had a Red Team review. Norm Augustine was asked to chair this red team. The red team comprised hospital leaders from around the country, not researchers but hospital leaders. They invited a few people to make short presentations from my team. We had been very proud of the care that we provided to our patients, who were helping us with our research protocols. We had received glowing reviews for years by many different groups, including the Joint Commission on Hospital Accreditation. So we were disappointed when the red team said we weren't as attentive to good care as we should and that the pendulum had swung too far toward research and drifted away from a focus on patient care. The community here was very upset, because the community felt that they were providing outstanding care in our research hospital.

Harden: There was a very strong letter from senior people in the Clinical Center.

Gallin: There were a number of letters. There was a letter from the department heads in the hospital. There was a letter from the Medical Executive Committee, which is like the hospital board. And there was a letter from the Assembly of Scientists at NIH. And then there were a lot of private letters from the patient advisory group and others. But Dr. Collins and his team made a decision to make a major overhaul of the hospital administration. And so that overhaul included dismantling the NIH Clinical Center’s Advisory Board for Clinical Research, which had been created under Secretary Donna Shalala. Board members received letters saying they would no longer be serving on that board.

Harden: Was any reason given for that particular—

Gallin: The NIH leadership thought the governance wasn't right. That board comprised people who were leaders of hospitals and scientists, people in the National Academies, people who were CEOs of hospitals, presidents of universities--it was a very high-level board comprising clinical investigators and hospital leaders. Those people were stunned and upset, but Dr. Collins felt that was necessary to make a bold change. The red team recommended that the position of Director of the Clinical Center, which is a position that had been in existence since 1953 when the hospital opened, should be abolished, and a new position, the Chief Executive Officer of the hospital, should be created, and someone should be brought in who was an expert in patient care and not a researcher.

I was notified that my position would be eliminated. I was asked to continue in my position until they identified a new person to lead the hospital. The Chief Operating Officer of the hospital was told that she would not be retained in that position, and the Deputy Director for Clinical Care received the same message. The head of the Pharmacy and the head of the Pharmaceutical Development Section were removed from their positions.

Harden: The magnitude of this upheaval suggests to me a very political situation, that this was bad publicity for the NIH, and therefore heads had to roll, and people at the top—including yourself—were the heads that had to roll to demonstrate that something had been done. Is that a fair assessment?

Gallin: Well, I'm biased.

Harden: I understand that.

Gallin: There were a lot of politics behind this. Dr. Collins said on several occasions that this was the worst black eye he ever had. And so, yes, there were politics behind this, but I think Dr. Collins felt that there was a problem, and he wanted to address it. He made the decision, and he believed that it had to be a bold decision. Some good things came from this and I'll tell you about those in a minute. The newspapers initially were very negative, and then as people on the campus got upset and protested, the articles in the newspapers began to say, or at least to report, that there was unrest among the staff and patients. And coincident with this, the number of patients coming to the hospital began to drop. Whether it was due to the red team report or other coincidental events is not clear.

Harden: Dr. Collins himself insisted that this new leadership structure was not, "a negative comment" about you and your team. "It's a vote of no confidence in the structure that no longer fits the needs."

Gallin: Right. He did say that. He said that publicly, and he met with the Patient Advisory Group, who were very angry. And he listened to them, and then he wrote them a letter saying that again, and he wrote to me saying that.

Throughout all of this, he was working on how to identify the problem and how to correct it. I was disappointed because I didn't have a chance to speak with him about this for a year. And he acknowledged later that that was a mistake. But the long-term outcome, which is what we need to focus on now, is that a new governance structure was created. A new board called the Clinical Center Research Hospital Board was created. The people on the board are experts on patient care and patient safety. I think that the new board has given very thoughtful and helpful advice on patient care.

I've had the opportunity to visit some other hospitals that had negative publicity. The Dana Farber Cancer Research Center in Boston, and the Johns Hopkins University both have had serious problems. And they said, "You'll never forget this. Your institution will never forget this. People will remember this forever, even after the people who were players are long gone, you just don't forget this. It has a lasting impact." But they also said, “That is not all bad, because people are always worrying.” Our hospital event was very different from these others because no patient got hurt. There wasn't a single patient that was hurt throughout this entire event. And I still would say that the technician who figured out that there was a problem with the albumin should get a big prize and be saluted for doing what's right, and doing it quickly. And then her immediate team who identified that there was a problem should also be recognized.

Harden: I have looked at the organizational listing of the Clinical Center as it now exists, and the org chart makes it very, very clear who reports to whom right up the ladder. To me it says, “What is now important is that we have to show lines of accountability.”

Gallin: Yes. The new CEO is Jim Gilman [Dr. James K. Gilman], who is a retired Major General in the Army. And in his experience in the Army, he led some big hospitals for the military, including Walter Reed. His perspective is to deliver outstanding care. But of course, Dr. Collins is also concerned about the science. He recognized that we have to do outstanding science, and so I was flattered when he asked me if I would take on a new job, the newly created position of Chief Scientific Officer of the Clinical Center, and continue in a job that I had had since I became Director of Clinical Center 1994, as the NIH Associate Director for Clinical Research. I said that I would be pleased to do that, and we outlined some charges that I could try to accomplish. I've been meeting every other week with Dr. Gilman, and we've actually, I think, bonded professionally very well. And we're trying our best to make sure the hospital thrives.

We lost the very important resource of the Pharmaceutical Development Section. I am now co-chair with Dr. Michael Gottesman, the Deputy Director for all of Intramural Research at NIH, of a group called the Sterile Human Products Administration Committee. We meet every other week with the Pharmacy folks, with the regulatory folks, and we try to make sure the needs of the scientists are being met. But we're not producing products here. We're identifying contractors around the country who can make products for us. The problem is that it's hard to find anyone who's really good at production of research products for human use. But we have found some places to produce products, and they've been helpful. It's very expensive, so we can't deliver as many products as we need to deliver.

We're exploring whether we can open up a non-sterile section to make certain things like pills and ointments. But at least in the immediate future, we're not going to be making any things for intravenous or intramuscular administration.

Now, the good news, the really good news, is that the entire NIH institution has become very concerned about the Clinical Center. There is unanimous agreement that it must stay open, and it must thrive. It plays a very important national and international role in developing new tools to improve health care. And so funding for the hospital has increased quite dramatically.

This has meant that a lot of the problems we just could not solve are now being addressed. Capital equipment is an important part of the hospital. We never had a capital equipment fund. We now have a separate fund for capital equipment. That just happened in the last year. Resources for the Pharmacy have increased tremendously. We've created a new Office of Regulatory Compliance that helps investigators carry out their activities in compliance with all the regulatory issues. We've consolidated all of our Institutional Review Boards into one and hired a new team to oversee the reorganization. The increase in support for the Clinical Center is a very reassuring outcome.

Harden: Would you talk more about what you are now doing as the Chief Scientific Officer with the researchers themselves?

Gallin: A big question that Dr. Collins had is, “How do we know that the science being conducted by our clinical research protocols is as good as it could be, that it's as good as anywhere else?” To answer this question, we instituted a new policy which I wrote with Dr. Collins' help, on Scientific Review of Clinical Research protocols conducted in the NIH intramural program.

I was also asked to come up with a mechanism to prioritize scarce resources at the Clinical Center, to assure we are using our resources to support the best scientific opportunities. In response we have put in place a policy that I oversee for scientific review all the protocols that all the institutes are doing.

If you asked me “Are we better off in terms of resources than we were five years ago?” I'd say, "Yes, in terms of funding." However, I am concerned that we have issues with acquiring new products for first-in-human studies, and I am concerned about the decrease in patient activity.

Harden: Just last year with your wife, Elaine, you established through the Foundation for NIH a new Trailblazer Award for an early career clinical investigator. Why did you do this? And have you made the first one or two awards?

Gallin: This is something my wife and I have been particularly excited about. Elaine has worked in science as a PhD physiologist, and then later in her career, she ran the Doris Duke Charitable Foundation’s medical research program and helped to fund early career investigators, mid-career investigators and senior investigators. We thought that it would be grand if we could make a contribution to the field, and I had been fortunate early in my career to receive an award from the American Federation for Medical Research as the outstanding early career investigator, which I shared with an investigator named Stuart Orkin [Dr. Stuart H. Orkin], who's at Harvard. That was an important event for me. And I wanted to see if we could come up with something similar to that.

We asked Maria Freire, who is President of the Foundation for NIH, if there might be any interest, and we were able to give some funds to get this launched. Last year, we gave out our first award. We were thrilled because there were over 100 applicants from across the country, from the very best places, and incredible people were nominated. The FNIH identified a fabulous jury who selected the awardee, Dr. Michael Fox, a neurologist and engineer from Harvard, as the first recipient. Dr. Fox helped to describe the Connectome, the wiring network between different parts of the brain. This is truly trailblazer work that will explain how different parts of the brain interact in neurological and psychiatric disorders, so he got the first award. The second award was given in the fall of 2019 to Jim Kochendorfer (Dr. James Kochendorfer) who works at the NCI at the Clinical Center for his work developing a new approach for treating lymphoma using CAR T cells that was approved recently by the FDA. This too was trailblazing work that has a huge impact on many patients with lymphoma who have failed other therapies.

Harden: When you first decided to get into clinical research, you came to NIH, and you have chosen to spend your career here. Do you think you could have done what you've done anywhere else? And are you glad you had this particular career?

Gallin: Yes, I'm thrilled with it. I was slanted towards research early on, in college, and then in medical school, and then as an intern and a resident. I had wonderful mentors who helped me and guided me as I was going through those early experiences. And then when I came to NIH, it was an incredible opportunity. I was put in an environment with a tremendous group of mentors, and a tremendous group of colleagues. We exchanged scientific information with each other, and we developed friendships, and those friendships have lasted. We didn't have to worry about how we were going to get our next dollar to support our research. We could bring in patients as scientific opportunities arose. We had the Clinical Center where we could provide outstanding care while conducting our clinical research.

That opportunity to be free of financial and time constraints to do patient care and research was precious. Nowhere else in the world was this possible like it is at the Clinical Center. When I was young, I dreamed about doing the research with patients and someday helping young clinical investigators. But I never imagined I would also have the opportunity to contribute administratively to building a new Clinical Center or a new Family Lodge, to building a new clinical research information system or to develop a curriculum in clinical research with international reach. The NIH provided all this, and the most important thing has been the phenomenal group of colleagues who made this all happen. Yes, I have been very lucky to have been able to spend my career at the NIH.

Harden: Those are all the questions I have. Is there anything else you want to get on the record before we stop?

Gallin: I think those last few comments covered it.

Harden: Thank you so much for a wonderful oral history.